UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200: JOY ESSMAN Case No. 2:12-cv-00277 BARBARA A. HILL Case No. 2:12-cv-00806 PAULA KRIZ Case No. 2:12-cv-00938 BRENDA RIDDELL Case No. 2:12-cv-00547 SHARON CARPENTER Case No. 2:12-cv-00554 MARY JANE OLSEN Case No. 2:12-cv-00470 VIRGINIA WHITE Case No. 2:12-cv-00958 SANDRA WOLFE Case No. 2:12-cv-00335 MARIE SMITH (F/K/A BANKS) Case No. 2:12-cv-01318 SHERRY FOX Case No. 2:12-cv-00878 LOIS DURHAM Case No. 2:12-cv-00760	ORAL DEPOSITION OF CHRISTINA PRAMUDJI, M.D. MARCH 23, 2016

ELIZABETH BLYNN WILSON)
Case No. 2:12-cv-01286)
)
DAPHNE BARKER)
Case No. 2:12-cv-00899)
)
WENDY HAGANS)
Case No. 2:12-cv-00783)
)
MARIA EUGENIA QUIJANO)
Case No. 2:12-cv-00799)
)
SHARON BOGGS)
Case No. 2:12-cv-00368)
)
CAREY COLE)
Case No. 2:12-cv-00483)
)
CATHY WARLICK)
Case No. 2:12-cv-00276)
)
DONNA AMSDEN)
Case No. 2:12-cv-00960)
)
HEATHER LONG)
Case No. 2:12-cv-01275)
)
PENNY RHYNEHART)
Case No. 2:12-cv-01119)
)
NANCY JO WILLIAMS)
Case No. 2:12-cv-00511)
)
MARIA STONE)
Case No. 2:12-cv-00652)
)
TERRI KEY SHIVELY)
Case No. 2:12-cv-00379)
)
CHARLENE LOGAN TAYLOR)
Case No. 2:12-cv-00376)
)
TINA MORROW)
Case No. 2:12-cv-00378)
)
CAROL JEAN DIMOCK)
Case No. 2:12-cv-004001)

ORAL DEPOSITION OF CHRISTINA PRAMUDJI, M.D., produced as a witness at the instance of the PLAINTIFFS, and duly sworn, was taken in the above-styled and numbered cause on the 23rd of March, 2016, from 1:20 p.m. to 4:25 p.m., before Tamara Vinson, CSR in and for the State of Texas, reported by machine shorthand, at the Westin-Houston Memorial City, 945 Gessner Road, Houston, Texas, 77024, pursuant to the Federal Rules of Civil Procedure and the provisions stated on the record or attached hereto.

APPEARANCES

FOR THE PLAINTIFFS:
ANDREW N. FAES, ESQ.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, Missouri 64112
816.701.1100
afaes@wcllp.com

FOR THE DEFENDANTS:
WILLIAM M. GAGE, ESQ.
Butler Snow, LLP
1020 Highland Colony Parkway, Suite 1400
Ridgeland, Mississippi 39157
601.948.5711
william.gage@butlersnow.com

ALSO PRESENT:
Ms. Tamara Vinson, Court Reporter

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EXHIBIT INDEX

CHRISTINA PRAMUDJI, M.D.,
having been first duly sworn, testified as follows:

EXAMINATION

QUESTIONS BY MR. FAES:

Q. Dr. Pramudji, good afternoon. My name is Andy Faes. I'm here to take your deposition today regarding the Prosima device. Do you understand that?

A. Yes.

Q. And you understand that you're sworn to tell the truth. Correct?

A. Yes.

Q. Now, if I ask you -- you've been through this process before, I take it, but if I ask you a question that you don't understand, just let me know and I'll try to rephrase the question. All right?

A. Sure.

(Exhibit No. 1 marked.)

Q. I'm going to hand you what's been marked as Exhibit No. 1 to the deposition, which is the deposition notice. Let me ask you, Dr. Pramudji, have you reviewed that document prior to today?

A. Yes.

Q. And attached to that notice there's a number of document requests. Have you brought any materials

with you today that are responsive to those requests?

A. Yes.

Q. What are those materials that you brought today?

A. Well, I brought my CV. I brought all the documents in my possession, including the thumb drives, the company educational literature, the literature in publications, all the documents that I would have used in preparation, the patient medical records, everything that I could -- that I could find, with the exception of some of the materials that were produced in prior cases and have been sent back to Butler Snow.

Q. Have you brought any invoices with you today regarding your work on the Wave 1 expert reports or any of the --

A. No.

Q. -- case-specific reports?

A. No.

Q. Okay. What I'm -- have you billed for those --

A. No.

Q. -- those reports yet? No, you have not. When do you anticipate billing --

A. Probably --

Q. -- for those reports?

A. Probably in the next few days.

Q. Within the next few days?

A. Yes.

Q. Okay. What I'm going to do is -- I know I'm throwing off the exhibit numbers, but I'm going to mark as Exhibit No. 5 --

A. Uh-huh.

Q. -- a placeholder. And if you and William could agree that when those bills become available --

A. Uh-huh.

Q. -- for your general reports and your case-specific reports --

A. Uh-huh.

Q. -- that are the subject of this notice of deposition, you'll send those to the Court Reporter and they'll substitute those out as Exhibit No. 5.

A. Okay.

(Exhibit No. 5 marked.)

MR. GAGE: And I would say, I don't have an objection to that, except for I do know I have -- Andy, I heard some generalized commentary back and forth between counsel, not you and me, that there was

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some dispute -- I can't remember the details of it -- some dispute as to whether or not we had gotten the invoices from Plaintiffs and their experts and we needed to have some meeting of the minds. I'm assuming we're going to ultimately get to a meeting of the minds on that. So I don't have an objection to producing them, but I do know that there is some dispute out there that we're still needing to get some from your experts. And so, you know, that's not a fight you and I need to discuss or deal with today.

MR. FAES: No. I agree.

(Exhibit No. 2 marked.)

Q. (By Mr. Faes) Doctor, I'm going to hand you what's been marked as Exhibit No. 2.

A. Uh-huh.

Q. Can you tell me what that is?

A. Yes. This is my expert report regarding the Gynemesh, the Prolift and the Prosima.

Q. Does this report contain each of the opinions that you've reached regarding the Prosima, Prolift and Gynemesh PS?

A. Yes, these are my opinions.

Q. Is there any particular reason why you chose to combine your opinions on those three products into

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a single report as opposed to separating them out?

A. Well, because the products are made of Gynemesh PS and a lot of the science correlates with -- with all the products, it seemed to make more sense to just combine it.

Q. Would you agree that the Prosima, for example, has a different safety and efficacy profile than the Gynemesh PS flat mesh?

A. It does have a different efficacy, yes. But -- but I think a lot of the general -- the general points about the different products come together nicely and the opinions can be held.

Q. So you've answered my question on efficacy.

A. Uh-huh.

Q. Do you agree that the Prosima has a different safety profile than the Gynemesh PS flat mesh?

A. It depends on what you're -- what you're talking about. There are some differences, yes.

Q. You'd agree that the Prosima device has some unique risks that are unique to the Prosima. Correct?

A. I don't know if they're unique risks. I'm thinking more about the rates may be different when you compare the products.

Q. But as a general principle, we can agree that

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the complication rates for the Prosima device are different than the Gynemesh PS flat mesh. Correct?

A. Are you talking about the Gynemesh PS being used as a Prolift or just being used as a --

Q. No. I'm talking about the Gynemesh just as a flat mesh.

A. Oh, they're -- actually, they're pretty similar.

Q. So it's your --

A. I -- I'm sorry. Before I thought you were talking about the Prolift versus the Prosima, which they have slightly different rates. But with the Gynemesh and the Prosima they're pretty similar.

Q. So you believe that the complication rates for the Prosima device and the Gynemesh PS flat mesh --

A. Uh-huh.

Q. -- are similar?

A. Yes.

Q. Do you agree that the Prolift device has a different safety and efficacy profile than the Gynemesh PS flat mesh?

A. It has a slightly -- slightly different, but it's -- it's not a huge -- not a huge difference.

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Q. Well, you'd agree, for example, that the Prolift kit has trocars and the Gynemesh PS flat mesh and the Prosima mesh do not have trocars. Correct?

A. That's correct, yes.

Q. Would you agree that the trocars used in the Prolift mesh kit can introduce unique risks that are not risks of the Gynemesh PS flat mesh or the Prosima device?

A. They -- they can, yes. I don't know that they're really significant looking at the literature, but that is a theory that's out there.

MR. FAES: Okay. Object and move to strike after the answer "yes."

Q. (By Mr. Faes) Now, in your report, which I've marked as Exhibit 2, you go through various facts and discuss facts. Did you discuss the facts that you were -- you felt were the most important in drawing your opinions in the report?

A. Yes.

Q. In terms of your decision making in writing the report, why did you choose to cite the articles in your report that you cited?

A. Well, I try to cite as much level one

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literature as I can, which is going to be randomized controlled trials and review studies where they're, you know, gathering together a lot of large studies because that's the highest level of literature and try to get a good sampling of the highest level studies that there are.

(Exhibit No. 3 marked.)

Q. Okay. I'm going to hand you what's been marked as Exhibit No. 3 to your deposition.

A. Uh-huh.

Q. Can you tell me what that is?

A. It's the reliance list.

Q. Now --

MR. FAES: Do you have something to say, William, before I. . .

MR. GAGE: Just don't forget to -- she mentioned an updated resume. I didn't want you to forget to --

MR. FAES: Oh.

MR. GAGE: -- mark that as a separate exhibit, which I'm handing to you. I mean, do it after you ask the questions on the reliance list.

MR. FAES: Sure.

MR. GAGE: I didn't mean to interrupt

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you.

MR. FAES: Well, I already had a different one marked, so. . .

MR. GAGE: Yeah. Is that -- well, he'll ask you -- he'll ask you whether you updated that one at the appropriate time. I'm sorry to interrupt. I just didn't want to forget. I handed it to you when I looked down and I saw it in my lap.

MR. FAES: I don't see any difference between this and the one I have. Anyway. . .

Q. (By Mr. Faes) Now, Dr. Pramudji --

A. Uh-huh.

Q. -- Exhibit 3 --

A. Uh-huh.

Q. -- is that the reliance list for both your Prosima/Gynemesh PS/Prolift report, as well as your TVT and TVTO general report?

A. Yes.

Q. And at this time, you haven't issued any general reports on any of the TVT products, other than the TVT retropubic device and the TVTO device. Right?

A. That's correct.

Q. Now, did you make this list or was it provided for you?

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A. Butler Snow helped me to make the list.

Q. Does this list contain all of the materials that you reviewed and relied upon in forming your opinions in this case?

A. Yes.

Q. You've mentioned that you've brought a number of materials with you.

A. Uh-huh.

Q. There's flash drives, there's materials stacked in front of you.

A. Uh-huh.

Q. Is everything -- is there anything that you brought today -- strike that. I'll start over --

A. Uh-huh.

Q. -- and ask a new question because you look like you're maybe a little confused.

Is there anything that you brought with you today that you've reviewed and relied upon in forming your opinions on the Prolift, Prosima or Gynemesh PS --

A. Uh-huh.

Q. -- that is not listed on Exhibit No. 3?

A. Not to my knowledge.

Q. Now, you've combined your reliance

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list for the -- we'll call them the pelvic organ prolapse products. When I say pelvic organ prolapse products, I'm referring from here on out as the Prolift, the Prosima and the Gynemesh PS. Can we agree to that?

A. Yes.

Q. So you combined your opinions -- strike that.

You've combined your reliance list for your report on the pelvic organ prolapse products and your general report on the TVT and TVTO products. Correct?

A. Yes.

Q. There's one reliance list for both reports. Correct?

A. Yes.

Q. In forming your opinions, did you rely on midurethral slings -- strike that.

In forming your opinions on the POP products, did you rely on midurethral strings [sic] and the TVT to form any of your opinions regarding the safety and efficacy of the Prolift?

MR. GAGE: Object to form.

A. Not for the -- not for the major substance of my opinions. I mean, for, you know, peripheral knowledge, I think it helps support the safety of the

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mesh, but obviously they're very different products, so you can't draw too many conclusions --
Q. (By Mr. Faes) Okay. So same --
A. -- on the general safety of the mesh.
Q. Sorry. I didn't mean to interrupt you. So same question: Prosima and Gynemesh PS, in forming your opinions, did you rely on midurethral slings and the TVT to form any of your opinions regarding the safety and efficacy of the Gynemesh PS or the Prosima?
A. I'm sorry. Wasn't that the same question that I just answered?
Q. You answered it for Prolift the first time.
A. Oh, okay. Well, it would be the same answer.
Q. Okay. Thank you. Now, when were you first contacted about being a general expert in this case regarding the Prosima?
A. Well, the M -- this M -- this big MDL wave was in November.
Q. Okay.
A. But there was another Prosima case prior to that, maybe a year, year and a half ago.
Q. Right. You're referring to the Caviness case --
A. Right.

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Q. -- where you were asked by Butler Snow to be an expert?
A. Yes.
Q. But you didn't prepare a written report in that case. Correct?
A. I honestly can't recall. I don't know. I can't remember. At this point, I'd have to look back at my records.
MR. FAES: Okay. And I'd ask if one was -- was created that it be produced to us, but, William, correct me if I'm wrong, I'm pretty sure there wasn't. It was just an expert disclosure. Right?
MR. GAGE: Andy --
THE WITNESS: I think --
MR. GAGE: -- I honestly don't know, but I will tell you, my sense is --
THE WITNESS: That's right.
MR. GAGE: -- in Texas State court, I think the rule is we only had to do disclosures and not reports.
MR. FAES: Yeah.
MR. GAGE: And I think you're --
THE WITNESS: Yeah, that's what it --

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because it was Texas --
MR. FAES: Right. And you guys --
THE WITNESS: -- Federal court.
MR. FAES: And you guys never do any more than that.
THE REPORTER: We have to do this one at a time, please.
MR. FAES: Sorry.
MR. FAES: Okay. So I'll just ask if the -- that -- if one was created for the Caviness case, a written report, that you provide that to us.
Q. (By Mr. Faes) How many hours would you -- strike that. I'm going to ask a different question.
When were you first contacted about being an expert in this case regarding the Gynemesh PS?
A. When you say "this case," you mean -- what do you mean specifically?
Q. I mean this Wave 1 general expert report.
A. This. Oh, okay. So that all just started in November.
Q. Have you -- do you have an estimate of the number of hours that you've spent preparing this report which is marked as Exhibit 3?

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A. Yeah. Probably, I would say -- I would estimate about 50 hours.
Q. Now, that 50 hours, is that for the entire report for all three of the pelvic organ prolapse products?
A. Yes.
Q. How many hours of that 50 would you say you spent actually drafting the report?
A. Probably about 20.
Q. And how many of those hours would you say you spent reviewing materials that went into the report?
A. About 30. A lot of the materials I was already familiar with from previous cases.
(Exhibit No. 4 marked.)
Q. Okay. I'm going to hand you what's been marked as Exhibit 4, which is the -- your CV that was produced to us. And I'm also going to mark as Exhibit 6 the CV that counsel just gave me, which was represented as your updated CV. At first glance, I couldn't tell my difference to it. We'll refer to Exhibit 6 most of the time.
(Exhibit No. 6 marked.)
Q. So if you look at Exhibit No. 6, which has been represented as your current updated CV, there's a

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list of publications. Correct?
A. Correct.
Q. Do any of the publications listed in your CV specifically address the Prosima product?
A. No.
Q. Do any of the publications listed in your report specifically address the Gynemesh PS products?
A. No.
Q. Do any of the publications in your report specifically address the transvaginal technique for the treatment of prolapse?
MR. GAGE: Object to form. Your -- the -- and I'll object to the form to last two -- the last two questions. You've asked the question: Do any of the publications listed in your report. I'm thinking you're meaning to say listed in your CV.
MR. FAES: I do mean that, so I'll -- thank you, William. I'll re-ask the question.
MR. GAGE: Yeah.
Q. (By Mr. Faes) Do any of the --
MR. GAGE: Well, she was giving an incorrect answer by saying no and so I felt it was important to. . .
THE WITNESS: Oh, I knew what -- I knew

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what he meant.
MR. FAES: That's the one time when I appreciate the speaking objection, William.
MR. GAGE: Yes.
Q. (By Mr. Faes) Do any of the -- Dr. Pramudji, do any of the publications listed in your curriculum vitae specifically address the Gynemesh PS product?
A. No.
Q. Do any of the publications listed in your curriculum vitae specifically address the transvaginal technique for the treatment of pelvic organ prolapse?
A. No.
Q. Would you agree that the Prosima is an alternative surgical treatment -- strike that.
Would you agree that the Prosima is an alternative surgical procedure for the treatment of prolapse as compared to other techniques that are available to physicians?
MR. GAGE: Object to form.
A. Yes.
Q. (By Mr. Faes) You've never published any peer-reviewed literature in the area of mesh complications. Correct?
A. That's correct.

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Q. You've never treated -- strike that.
You've never published any peer-reviewed literature in the area of treating mesh complications either. Is that correct?
A. That's correct.
Q. Now, you've used the Prosima in your practice. Correct?
A. Yes, I have.
Q. And you've implanted about 75 of them. Is that --
A. That's sounds about right, yes.
Q. Can you tell me when you first implanted the Prosima device?
A. Let's see. It was shortly after it came out, which I believe was in 2008, if I remember correctly. So that would have been -- you know -- shortly after it was launched I -- was when when I tried it.
Q. Now, you wrote in your report, I believe, that the Prosima didn't have a full launch until -- I can't find it. I believe you wrote in your expert report that the Prosima device didn't have a full launch until later in -- later in 2010. Is that correct?
A. (No response.)

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Q. It's Page 41 that you said it was not widely launched until August of 2010.
MR. GAGE: Object to form.
Q. (By Mr. Faes) Broadly launched. And it's top of Page 40. My mistake.
MR. GAGE: Object to form.
A. Oh, yes, that's correct. I got the dates confused. So it would have been after that.
Q. (By Mr. Faes) So that -- what you said earlier was incorrect, you don't believe --
A. Yeah.
Q. -- that you first implanted it in 2008?
A. That's -- yeah, that's incorrect. I got the dates confused, yeah.
Q. So you believe that you -- and actually, I was going to ask you later about that date on Page 40 of your report.
A. Uh-huh.
Q. Are you sure that's correct, that it was -- wasn't widely launched until August of 2010?
MR. GAGE: Object to form.
Q. (By Mr. Faes) Do you think it might have been August of 2009?
A. I would have to -- I'd have to look back at

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my references.
Q. Okay. But, at any rate, you believe you didn't begin using the Prosima device until it was officially launched in either 2009 or 2010, whatever the date may be, by Ethicon. Correct?
A. That's correct, yes.
Q. But you know that it -- that the Prosima device was actually cleared in 2007?
A. Yes.
Q. And was available to a limited number of physicians who were conducting trials and studies on the device. Is that correct?
A. Yes.
Q. So you -- you were not, as far as you know, one of the people that was involved in conducting a clinical trial on the Prosima or using the Prosima prior to its full launch by Ethicon. Is that right?
A. That's correct.
Q. Now, you use Gynemesh PS in your medical practice, as well. Is that correct?
A. I have used it in the past on a few occasions.
Q. How many times would you estimate you've used the Gynemesh PS?

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A. The free cut Gynemesh PS, is that what you're referring to.
Q. Yes. Yes, the flat -- the Gynemesh PS, the flat mesh.
A. Maybe a dozen times.
Q. Do you recall during what time period you've used the Gynemesh PS?
A. Going back to 2002 and then going forward to probably 2011.
Q. So when you used the Gynemesh prior to 2005, did you just use it where you would cut portions of it to help you in treating prolapse when you were doing native tissue repair?
A. That's correct.
Q. Okay. And why did you stop using it in 2011?
A. Because of the environment around that transvaginal mesh with the patients being more wary of it and feeling reluctant to have mesh implants.
Q. So you would agree that you moved away from using mesh for pelvic organ prolapse repair?
A. Yes. Not completely, but, yes. The environment was not conducive to using it.
Q. So when you -- do you still use mesh occasionally for pelvic organ prolapse repair?

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A. Absolutely.
Q. What mesh -- meshes do you use if you need a flat mesh, for example?
A. Well, I -- I haven't really used just a flat mesh. I've used -- I've used -- I use the Elevate.
Q. Still?
A. No.
Q. When did you stop using the Elevate?
A. Well, they've -- they've now stopped producing it, so. . .
Q. When did they stop producing it?
A. I think -- I think they're in the process of stopping, but they announced a couple of weeks ago that they are not going to produce it anymore.
Q. How did you learn of that announce many?
A. Through an e-mail from ASTORA.
Q. From -- was it from your sales rep or. . .
A. No. It was from corporate.
Q. Okay. And did they say when in that e-mail that they would officially stop --
A. Yes --
Q. -- making it available for sale?
A. -- but I can't remember the date. I think if the hospitals still have it, it could be used, but,

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you know, I think patients might feel uncomfortable with that. So next time that I need a transvaginal mesh, I'll probably use the Boston Scientific mesh.
Q. Which Boston Scientific mesh do you believe you'd use?
A. Well, I think they only have one transvaginal kit right now and I can't recall the name of it.
Q. Is it the Uphold product?
A. Uphold, yes.
Q. I got a little sidetracked with the Elevate stuff.
A. Okay.
Q. So if you need a -- if you needed a -- strike that.
When is the last time that you recall using a flat mesh that you cut yourself or inserted in whole in a pelvic organ prolapse repair?
A. So not a kit --
Q. Right.
A. -- you mean?
Q. Right. A flat mesh like the Gynemesh PS.
A. The last time would probably be in 2011, because at that point I only used it to supplement a to Total Prolift that had a large apical defect. So,

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at that point, I wasn't even using it by itself. I used it in conjunction with the Prolift. I would fashion a greater apical support with the free mesh, if that makes sense. So where the Total Prolift would go across the apex, I would supplement with the Gynemesh. So the last time that I would have used a free cut mesh just to supplement was probably pre-Prolift.

Q. Okay. If you -- let me ask you this: If you had a patient with a large defect that you didn't feel you could repair using either native tissue or suture repair or a biologic mesh, would you consider using a synthetic mesh?

A. Yes.

Q. What synthetic -- what would be your synthetic mesh of choice in that situation?

A. I don't know. I don't know who -- I don't even know if they still make Gynemesh, because I haven't used it in so long. I don't even know if that product --

Q. So --

A. If that product is available, I would use Gynemesh.

Q. So, sitting here today, you don't know

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whether or not the Gynemesh PS is still available or not?

A. I do not know.

Q. Have you ever used the Prolene Soft product?

A. I always get the different nomenclatures confused. Is that the same one as Prolift Plus M?

Q. No, it is not.

A. Okay. Is that the Vypro?

Q. No.

A. Okay. What is the --

Q. So -- so let me ask you this: Sitting here today, do you know what the Prolene Soft mesh is?

A. No, I don't.

Q. Do you know if there is any difference between the Prolene Soft mesh and the Gynemesh PS mesh?

A. I can't recall right now.

Q. So if they're identical, you wouldn't know that one way or the other?

A. I can't recall what Prolene Soft is.

Q. Okay. So it's probably also fair to say that you don't know if there's a price difference between the Gynemesh PS or the Prolene Soft mesh?

A. A price difference?

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Q. Yes.

A. No, I don't know.

Q. Do you know what sizes and configurations the Gynemesh PS currently is available in?

A. No.

Q. You stated earlier that you stopped using the Gynemesh PS, I think, because of the environment?

A. Yes.

Q. Did you say -- did I get that right?

A. That's correct.

Q. What do you mean by that?

A. Well, when there's, you know, wall-to-wall litigation commercials, patients look askew at mesh procedures. And so they -- they get scared and they want to look at other alternatives.

Q. When did you first begin to use a mesh kit for the treatment of prolapse?

A. 2005.

Q. And what was the first kit that you used?

A. The Prolift.

Q. And other than that kit, is the only other kit you've used on a -- not counting, like, cadaver labs --

A. Uh-huh.

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Q. -- but in a -- on a live human woman, is the only other kit that you've used the Elevate?

A. Elevate, the Prosima --

Q. Oh, yeah, the Prosima and the --

A. -- and the Uphold.

Q. You have used the Uphold?

A. Yes.

Q. When did you first use that?

A. I don't recall. It was several years ago.

Q. And has it -- when's the last time that you used the Uphold kit?

A. I really have only tried it a couple of times and that was a few years ago.

Q. Okay. And you've also used -- I think you just forgot to mention it -- you've used the Prolift Plus M --

A. Yes.

Q. -- kit before, as well.

A. Yes.

Q. Correct?

A. Uh-huh, that's correct.

MR. GAGE: Let me just remind you --

THE WITNESS: Yes.

MR. GAGE: -- the way the Court Reporter

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has to work, Andy -- let Andy really completely fully finish his question --

THE WITNESS: Uh-huh.

MR. GAGE: -- before you answer, because I'm reading the transcript here and a lot of times you're answering before Andy is finished. And we want to make it nice and clean for the record, so I may from time to time nudge you on that point.

MR. FAES: And the Court Reporter appreciates it, too.

MR. GAGE: Yeah.

Q. (By Mr. Faes) Now, during the time that you were using the Prosima, did you also continue to do native tissue repairs with sutures?

A. Yes, I did.

Q. Did you view the native tissue repairs with sutures as an alternative to the Prosima and vice versa?

A. Yes.

Q. And you've also done abdominal sacrocolpopexy. Correct? I tried to say that correct. I don't know if I did or not.

A. That was close. Yes. I really started doing that primarily, though, after 2011 when the

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transvaginal mesh became controversial.

Q. When did you first start to perform that procedure?

A. I did a handful prior to 2011, but I really started using it more after 2011.

Q. In terms of an alternative treatment for a patient, would you agree that abdominal sacrocolpopexy would be one of the alternatives if, in fact, there were prolapse in the part of a -- in the part of a pelvis that would be appropriate for that treatment?

MR. GAGE: Object. Form.

A. I don't understand the last part of your question.

Q. (By Mr. Faes) You know what, I'll strike that and ask a new one.

What meshes have you used for abdominal sacro -- I'll just say ASC. Okay? What meshes have you used for AFC -- ASC?

A. I've used the Ethicon product.

Q. Okay.

A. The Coloplast product, which is called Restorelle, R-E-S-T-O-R-E-L-L-E. And that's what I use currently. And I've also used the AMS product.

Q. The Y mesh or. . .

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A. Y mesh. They're all Y meshes.

Q. But you don't use the Ethicon Artisyn mesh?

MR. GAGE: Object. Form.

A. I tried it a couple times, but I didn't -- I didn't prefer it. It was harder to work with in surgery than the Restorelle in my hands.

Q. (By Mr. Faes) So it would be fair to say that currently when you do abdominal sacrocolpopexy procedure, your mesh of choice is the Coloplast Restorelle?

A. That's correct.

Q. When you consent a patient for a mesh kit, such as the Prosima device, do you -- did you talk to them about the specific manufacturer and compared the kits with them that were available to use or did you just talk about vaginal mesh, in general, and then you chose the kit for that patient?

MR. GAGE: Object to form.

A. I would talk about the vaginal mesh in general and maybe with the Prosima some of the nuances compared to the Prolift, but I -- other than that, I didn't compare it to different kits. I don't think patients would really be able to -- most patients would not be able to fully understand or appreciate

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the differences between the different kits.

Q. (By Mr. Faes) Okay. So that kind of brings --

A. I didn't see much -- I didn't much use for that.

Q. Okay. So that kind of brings me to my next question: You -- what's the time period that you performed the Prolift device? From 2005 until it was no longer available in 2012?

A. Yes, that's correct.

Q. And you were performing the Prosima from either 2009 or 2010, whenever the launch date was, until its discontinuance. Right?

A. That's correct.

Q. So during the time when you were implanting both Prosima devices and Prolift devices, how did you decide which kit to use for which patient?

A. The Prosima is best suited for a grade 2 or 3 cystocele or rectocele without loss of apical support. If they needed more apical support or they had other factors that I thought they needed more support, then I would do the Prolift.

Q. So is it fair to say that the Prosima was your device of choice for a patient that had a grade 2

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or 3 rectocele or cystocele without loss of apical support?
A. Yes.
Q. And your -- was your Prolift your device of choice for all other patients or was there a specific subset of patients that that was your device of choice for?
A. That was definitely my device of choice for the more severe prolapse patients, grade 4s or some grade 3s, as well, just depending on -- all grade 3s are not the same. They can have different angles and different areas that need support and some of those would get a Prolift, as well.
Q. Now, like the Prosima device, the Elevate does not have trocar passes. Is that correct?
A. That's correct.
Q. One significant difference between -- strike that.
The fact that there were no external trocar passes with the Elevate or the Prosima, did you see that as a potential benefit from a safety perspective as compared to the Prolift?
A. Yes, I did. You -- you do avoid some bleeding that could occur with a trocar pass. I

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didn't have any other complications with the trocar passes than bleeding at times, but for that reason it would have a slightly -- a slight advantage to the Prosima.
Q. Now, you talked a little bit about -- a minute ago about the Prosima device being best for grade 2 or 3 defects. Is that correct?
A. Yes.
Q. Is there anything, as you sit here today, that you know of in the IFU that tells physicians that the device is best for those two grades of prolapse?
A. I believe it does state that in the IFU and I know that that is what we taught in the prof ed, as well.
Q. So you believe it states in the Prolift IFU that it is only indicated for grade 2 or 3 defects?
MR. GAGE: Object. Form.
A. I know it's in some of the literature that the company put out. I'd have to look and see if it's in the IFU that I'm picturing in my head right now. Can I look at it?
Q. (By Mr. Faes) Yeah.
MR. FAES: Do you want to go off the record for just a second? I need some water and she

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can look at it.
(Break.)
Q. (By Mr. Faes) Dr. Pramudji, we're back on the record after a short break. Are you ready to proceed?
A. Yes.
(Exhibit No. 7 marked.)
Q. Before I -- before the break, I had asked you whether or not the Prosima IFU states that the device is indicated for grade 2 or 3 rectocele or cystocele and I handed you what's been marked as Exhibit No. 7 to your deposition, which is the 2010 Prosima IFU. Are you -- have you reviewed that document and are you prepared to answer the question?
A. Yes. I do not see in there where it says that it's indicated for that.
Q. Had she --
MR. GAGE: Hang on just a second. Okay. Go ahead.
Q. (By Mr. Faes) But you did mention that you believe that it was -- that information was contained in professional education materials?
A. Yes.
Q. Let me ask you this: Do you know if Ethicon

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keeps track of who those professional materials go to?
A. I have no idea.
Q. You would agree that the IFU, which is Exhibit No. 7 in front of you, is required by law to be in every Prosima product that is sold to physicians. Is that correct?
A. Correct.
Q. So we can ensure -- strike that.
By contrast, the professional education materials provided by Ethicon are not in every box of the product that goes out to physicians. Is that correct?
A. Of course not.
Q. Doctor, do you know the clearance date for the Gynemesh PS flat mesh product?
A. I think it goes back to 2002.
Q. And do you know when the Gynemesh PS product was first launched in the United States?
A. No, I don't.
Q. And I'll take it, since you don't know what the Prolene Soft product is, you don't know what the clearance date is for that product either?
A. Correct.
Q. And you don't know when the Prolene Soft

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product was first available for use by physicians in the United States?
A. That's right.
Q. Do you know the clearance date for the Prosima product? I think we talked about this a little earlier.
A. I think it was around 2008.
Q. But you don't know any more specific than that --
A. No.
Q. -- sitting here today? Do you recall if you -- if you listed that clearance date for either the Gynemesh PS or the Prosima product in your report?
A. I think I did. I can -- I'd have to look and see exactly where I put it in here.
Q. Okay. I don't -- I don't want to take the time right now, but we'll just -- we'll just have your answer stand that you believe it's in there.
Let me ask you this, Doctor: Would you -- have you ever used a medical device for something that it was not indicated for?
A. No.
Q. Is that something you would consider doing, is using a medical device for something off label or

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something that was not specifically in its indications for use?
A. Absolutely. As a trained surgeon, I use my professional judgment and sometimes there are situations where you use things off label, medications or potentially, devices. I haven't used a device off label that I can recall. I have used a medication off label and discussed that with the patient, but that's within the prerogative of the physician to use their judgment.
Q. And I take it -- you understand that surgical mesh is a medical device. Correct?
A. Yes.
Q. So you've never used a surgical mesh off label in your -- how many years have you been practicing?
A. Fifteen years.
Q. You've never used a -- so I'll restart the question: You've never used a surgical mesh off label in your 15 years of practice that you can recall. Correct?
A. That's correct.
Q. Do you know, sitting here today, whether or not the Gynemesh PS flat mesh is indicated for

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transvaginal use?
A. Yes, it is.
Q. So you believe, as you sit here today, that the Gynemesh PS mesh is indicated for transvaginal use?
A. Yes.
Q. Do you recall sitting -- as you sit here today, if you've reviewed the 2013 Gynemesh PS flat mesh IFU?
A. I'm sure I have, but I'd have to refresh my memory on that.
Q. Okay. Do you recall, as you sit here today, if you've reviewed the 2015 Gynemesh flat mesh IFU that's available on Ethicon's website?
A. I'm sure I have, but I'd have to review specifics.
Q. Do you agree with the FDA's viewpoint that there is a need for more rigorous studies regarding the safety and efficacy of mesh kits?
MR. GAGE: Object to form.
A. No, I disagree with them, because I think that we have a very strong body of data showing that the mesh kits are safe and effective.
Q. (By Mr. Faes) Have you ever seen the 522

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order that was issued by the FDA with regard to the Prosima?
A. I'm sure that I have at some point.
Q. Do you recall, sitting here today, what it said?
A. I can't recall.
Q. Have you seen Ethicon's response to the 522 order on the Prosima?
A. I'm sure that I have, but I couldn't -- I couldn't recite it to you.
Q. Do you recall, as you sit here today, if in response to Ethicon's -- strike that.
Do you recall, as you sit here today, if in response to the FDA's 522 on the Prosima, Ethicon tried to get the FDA to accept studies that it had already done on the Prosima in lieu of a 522 study?
MR. GAGE: Object to form.
A. I'm not sure if I know about that or not. I don't recall.
Q. (By Mr. Faes) Has anyone ever told you why the Prosima was removed from the market?
MR. GAGE: Object to form.
A. Not that I recall.
Q. (By Mr. Faes) Do you have an understanding,

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as you sit here today, of why the Prosima was removed from the market?

MR. GAGE: Object to form.

A. My understanding is that it was a calculation of being able to sell the product and having the resources to do the research that was required for the 522. That was my understanding. I can't recall who told me that.

Q. (By Mr. Faes) Let me ask you this: Do you intend to offer any opinions in this case about why the Prosima was removed from the market?

MR. GAGE: Object to form.

A. I am not sure.

Q. (By Mr. Faes) Would you agree that from the time that the Ethicon did a full launch of the Prosima product until the time they stopped making it and it was no longer available, it was less than three years?

A. That's correct.

Q. Do you know how many Prosima devices Ethicon sold during that time?

A. No, I don't.

Q. Do you recall specifically how you found out that the Prosima device was no longer going to be available for sale?

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A. No, I don't recall.

Q. Do you recall the month or the year when that occurred?

A. No.

Q. Do you recall if you had, like, a warning period -- was -- strike that.

Was there a time between when you were told that the Prosima was going to be -- was no longer going to be available for sale and when it was actually not available for sale?

A. Yes.

Q. Do you recall what hospitals you worked at during that time period when -- between when Prosima -- the announcement on Prosima was first made that it was no longer going to be sold and when it was ultimately no longer available?

A. Yes.

Q. Which hospitals were those?

A. Memorial Hermann, Memorial City.

Q. Okay.

A. And Memorial Hermann Katy and St. Catherine's Hospital.

Q. Do you know if any of those hospitals still had Prosima devices on their shelves after Ethicon

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stopped selling the product?

A. Yes, they did.

Q. Do you know what they did with those products?

A. They kept them so that I could use them.

Q. So you used -- continued to use the Prosima device after the announcement was made that it was no longer going to be available?

A. Yes.

Q. How many Prosima devices did you use --

A. I don't recall.

Q. -- during that time period?

A. I don't know.

Q. Do you recall when the last Prosima device you placed was?

A. No, I don't remember.

Q. Do you know what the shelf life of the Prosima product is?

A. No.

Q. Is it your usual practice to check the expiration date before you implant the product --

A. Absolutely.

Q. -- in a person?

A. Sorry. Sorry to interrupt. Yes, absolutely.

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Q. And to your knowledge, you've never implanted a product that was past the expiration date. Is that correct?

A. Not to my knowledge.

Q. Did you ask the hospital to buy up or stockpile any Prosima devices before it was no longer available when the announcement was made?

A. No, I didn't ask them to do that. I just felt like I would use what they already had on hand.

Q. You didn't do any kind of projection of, I think that -- you know -- I anticipate using this many products a month and the shelf life is X number of years, so I'll need this many products, you didn't do that analysis?

A. No.

Q. Same question on the Prolift: Do you know if any of the hospitals had that device on its shelves after Ethicon stopped selling the product?

A. Yes, they did, and I continued to use it.

Q. And you used it until they ran out?

A. That's correct.

Q. And same question on the Prolift: Did you ask any of the hospitals to buy up extra Prolift while it was available --

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A. No.
Q. -- obviously keeping in mind that there's an expiration date on the product and you would need to use it before it expired?
A. No, I didn't go to that extent.
Q. What about the Prolift Plus M device?
A. Same story.
Q. Okay. So you did continue to use the Prolift Plus M device up until the time it was no longer available?
A. That's correct.
Q. We talked a little bit about the selection criteria you used for the Prosima versus the Prolift device. What was your selection criteria for patients on the Prolift Plus M device? What kind of patients did you put that into?
A. Well, once the Prolift Plus M became available and I felt -- I saw result -- good results in my own patients, I started to transition my Prolift patients to Prolift Plus M patients. And so I began to use it more -- much more frequently than the Prolift. And it would have been basically the same patients with the more severe prolapse or loss of apical support.

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Q. For the Prolift Plus M?
A. Correct.
Q. Did -- was there a time that the Prolift Plus M device became your device of choice over the Prolift?
A. Yes, for a while it was.
Q. Do you recall about what time period that was when that occurred?
A. No, I can't remember.
Q. You said that you waited to switch over until you saw good results in your own patients. Did you do -- do you mean you implanted it in the patients and then waited to see what happened or are you referring to other physicians in your group?
A. In my own patients --
Q. Okay.
A. -- where I could examine them myself and see, see how well it worked.
Q. If you were able to find a Prosima or a Prolift device today that was not already expired, would you consider implanting it in a patient?
A. Absolutely.
Q. Do you believe it's within the standard of care to continue to implant those devices today?

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A. Absolutely. They're great products.
Q. Do you believe the Prosima device is still cleared by the FDA today?
A. From a regulatory perspective, I'm not sure. I don't know.
Q. If it were not cleared, would you still consider implanting the Prosima in a patient?
MR. GAGE: Object to form.
A. You know, it worked so great in -- with my patients that I probably would consider it, because looking at the data and with my own experience, I think it's proven to be very effective and safe and I feel very comfortable with it.
Q. (By Mr. Faes) So do you believe a physician would be within the standard of care if he knowingly implanted a medical device that was not currently cleared or approved by the FDA?
MR. GAGE: Object to form.
A. In certain situations, yes. Because our knowledge as physicians allows us the leeway to use things off label.
Q. (By Mr. Faes) I'm not talking about things that aren't indicated. I'm talking about a device that is no longer cleared or approved by the FDA.

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A. Uh-huh.
MR. GAGE: Object to form.
Q. (By Mr. Faes) Do you understand that?
A. I see the distinction that you're talking about. I think strictly legally there could be some -- some problems if you implant something that's not FDA approved, but whether that's outside the standard of care, I think -- I think it could still be within the standard of care.
Q. Backtracking a little bit to the Gynemesh PS flat mesh product, have you ever seen the 522 order that was issued by the FDA with regard to that product?
A. I believe I have.
Q. Do you recall, sitting here, what it said?
A. No, I don't recall.
Q. Do you know what Ethicon did in response to the 522 order on the Gynemesh PS flat mesh?
A. No, I don't.
Q. Have you ever used the standard, traditional Prolene mesh in your medical practice?
A. What do you mean by standard, traditional Prolene mesh?
Q. I'm talking about the standard mesh that's

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for hernia repair, not Prolene Soft, not Gynemesh.
A. No.
Q. Standard traditional Prolene mesh.
A. No, I have not.
Q. Is that a mesh that you would consider using in your practice?
A. I don't know. I'm not familiar with it.
Q. Let me ask you this: Do you believe it would be a reasonable decision for a doctor to stop using the Prosima device following the July 2011 FDA public health notification?
A. Sure.
Q. The same question: Do you believe it would be a reasonable decision for a doctor to stop using the Prosima -- strike that.
Do you believe it would be a reasonable decision for a doctor to stop using the Prolift or Prolift Plus M device following the July 2011 FDA public health notification?
A. If they're uncomfortable with it, that's their prerogative.
Q. Would you agree that surgical complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare?

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A. How are you defining "rare"? Or what do you mean by "rare"? Can you clarify that?
Q. Well, you're a physician. How do you understand the word "rare" when it relates to complications?
A. In my opinion, and looking at the literature and with my own experience, I think that the surgical complications are rare, meaning that they're less than ten percent.
(Exhibit No. 8 marked.)
Q. I'm going to hand you what's been marked as Exhibit No. 8 to your deposition. This is the 2011 public health notification.
A. Uh-huh.
Q. If I could have you turn to the second page.
A. Uh-huh.
Q. I'm just going to read the -- one, two, three, four -- fifth paragraph down. It says: The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are not rare.
Do you see that?
A. Yes.
Q. So you disagree with the FDA in this regard.

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Is that correct?
A. Yes, that's correct.
Q. Let me ask you this: When you consulted patients after this public health notification was issued, did you talk to them about this notice?
A. Absolutely.
Q. Did you tell your patients that you disagreed with the public health notification, that you disagreed with the FDA that the complications were not rare?
A. Yes, I did, because in my hands and the literature, they are rare.
Q. Do you believe that a physician, when they -- a physician who consents is -- strike that.
If a physician consents his patients for a pelvic organ prolapse kit procedure and tells that patient that serious complications associated with surgical mesh are rare, do you believe that that physician has appropriately consented the patient?
MR. GAGE: Object to form.
A. Yes.
Q. (By Mr. Faes) Do you agree or disagree that there is no evidence that transvaginal mesh repair with mesh provides any added benefit compared to

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traditional surgery without mesh?
A. I disagree, because I think the literature bears it out, but the transvaginal mesh repair is more effective that traditional repair. There's multiple studies that reinforce that.
Q. And you know --
A. And I saw that in my own experience.
Q. And if you turn to Page 3, you see that that statement is contained within the public health notification, as well.
A. (No response.)
Q. It's the third bullet point. I'll read it again for you. There is no evidence that transvaginal repair to support the top of the vagina, parentheses, (apical repair or back wall of the vagina), parentheses, posterior repair with mesh provides any added benefit compared to traditional surgery without mesh.
Do you see that?
A. Yes, I do.
Q. And you disagree with that statement from the FDA?
A. When you narrow in on the posterior wall, it is not as much of a benefit as it is on the anterior

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wall, which is what I was referring to previously.
Q. So I'm not sure if I got an answer to my question. Are you saying you agree with this statement from the FDA or disagree with it or you can't answer?
A. I would agree with that bullet point --
Q. When you --
A. -- about the posterior wall.
Q. When you consented patients for pelvic organ prolapse procedures after July of 2013 --
A. Uh-huh.
Q. -- did you tell them that there was no evidence that using mesh provides any added benefit as compared to traditional surgery without a mesh?
MR. GAGE: Object to form.
A. What I told patients -- we're speaking of a posterior repair right now. And what I told patients is that there is a slight benefit with the mesh and there is definitely a benefit with decreased pain with the posterior mesh versus a traditional posterior plication repair. Does that answer your question?
Q. (By Mr. Faes) Yes. Do you agree that mesh used in transvaginal pelvic organ prolapse repair introduces risks not present in traditional non-mesh

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surgery for pelvic organ prolapse repair?
A. The only additional risk that it introduces is a mesh exposure.
Q. So was my -- the answer to my question, yes, you agree with that statement?
A. (No response.)
Q. Do you want me to read the question again?
MR. GAGE: No. She can look at it here.
A. No. It only introduces that one risk. All the other risks are going to be potential with any pelvic floor surgery.
Q. (By Mr. Faes) So is it your testimony that mesh contraction is a risk of any other pelvic surgery?
A. Wound contraction is. Mesh doesn't contract. The wound contracts and the scarring contracts.
Q. You don't believe that mesh contracts?
A. No. The wound and the scar contract.
Q. If you go down to the second paragraph below the bullet point it says: Mesh contraction, parenthesis, (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the scientific literature in an adverse event reports to the FDA since the October

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20th, 2008 public health notification.
So at least according to this, both the FDA and the medical literature believed that mesh contraction or shrinkage does exist. Is that correct?
MR. GAGE: Object to form.
A. Yes, they do believe that, but I respectfully disagree, because the mesh does not contract. It's the scar tissue around it. And you can see wound contraction and vaginal shortening, tightening, pain with any pelvic floor correction.
Q. (By Mr. Faes) So you would disagree with both the FDA and the medical literature that mesh can contract or shrink?
MR. GAGE: Object to form.
A. Yes, the mesh does not contract or shrink. The wound and the scarring is what contracts and shrinks. The mesh, itself, does not.
Q. (By Mr. Faes) When the wound or scar contracts and shrinks --
A. Uh-huh.
Q. -- if the mesh is encapsulated --
A. Uh-huh.
Q. -- can the mesh shrink, as well, along with the wound or scar tissue?

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A. I mean, it's a matter of semantics. The mesh, itself, is not shrinking or contracting. If you take it out, it's going to be the same Prolene caliber fibers. They're not going to be shrunken.
Q. There not going to be shrunken or deformed as the wound or the scar tissue which completely surrounds it contracts?
A. The pores will be -- the pores of the mesh maybe shrunken or deformed and pulled together by the scar tissue, but the Prolene, itself, is not shrunken.
Q. Do you degree -- strike that.
Do you agree or disagree that mesh placed abdominally for pelvic organ prolapse repair results in lower rates of mesh complications compared to transvaginal pelvic organ prolapse surgery with mesh?
A. Actually, the mesh erosion rates are similar with the transabdominal and the transvaginally placed mesh looking at the sacrocolpopexy studies. They have similar rates.
Q. So if you turn to Page 4 of exhibit -- the exhibit that I just handed you.
A. (Complying.)
Q. You go under the bullet point: Consider these factors before placing surgical mesh. The last

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bullet point you see, it reads: Mesh placed abdominally for pelvic organ prolapse repair may result in lower rates of mesh complications compared to transvaginal pelvic organ prolapse surgery with mesh.

Is it fair to say that you disagree with the FDA on this statement?

A. Well, it says it may result. They're not saying it does result in lower rates. And I think, if we look at the literature, we can see they're very similar rates.

Q. So you -- does that mean you agree with the statement from the FDA that it may result in lower rates of mesh complications compared to transvaginal pelvic organ prolapse surgery with mesh?

A. As they've written it here, may result, I can't really disagree with that. I think, as -- as time has borne out and as we've seen further studies with sacrocolpopexy, we're seeing that this -- the mesh exposure rate is very similar or suture exposure rate. And with abdominally placed mesh you also have the risk of bowel obstruction and adhesions, intraabdominal adhesions.

Q. I think you've answered my question. I'll

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object to move to strike after the word "that" just for the record.

If a synthetic graft product like the Prosima does not do better than native tissue repair, in terms of safety and efficacy, do you think it should be introduced to the market?

A. That's a hypothetical question.

Q. It is.

A. If any product doesn't show improved safety or efficacy, I don't know why they would want to -- why anyone would want to release it or market it. What would be the point?

Q. Okay. Do you agree or disagree with the following statement: There is no authoritive -- authoritative paper to support the Prosima outcomes are superior or even comparable to a colporrhaphy?

A. I disagree with that statement.

Q. So if the investigator of a -- on a Prosima trial were to make that statement to Ethicon, you would disagree with that statement?

A. Yes. I think we've got some good literature that shows that it is efficacious and safe. And that's also what I saw in my own experience.

Q. If a primary investigator for a Prosima trial

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which studied whether or not the product was effective for -- strike that.

Do you agree that native tissue repairs have similar outcomes to synthetic mesh without the risks inherent in mesh use?

MR. GAGE: Object to form.

A. (No response.)

Q. (By Mr. Faes) Why don't I ask a better question? Do you agree that native tissue repairs for the repair of pelvic organ prolapse have similar outcomes to synthetic mesh used for pelvic organ prolapse without the risks inherent in mesh use?

A. No.

MR. GAGE: Object to form.

A. I think the -- in my opinion, the literature is clear that the outcomes are better with mesh augmentation and the risks are similar. The only additional risk is mesh exposure or erosion.

Q. (By Mr. Faes) Do you agree or disagree that native tissue repair remains the standard of care for the treatment of pelvic organ prolapse in the typical patient?

A. I disagree. The standard of care is sacrocolpopexy at this point.

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Q. What exhibit are we on, Doctor? Are we on 9?

A. 8. It's 9.

MR. GAGE: This was one 8.

A. That's correct.

MR. GAGE: So 9 would be next.

(Exhibit No. 9 marked.)

Q. (By Mr. Faes) Doctor, I'm going to hand you what's been marked as Exhibit 9 to your deposition.

MR. FAES: I actually got one of these for you, too, William.

Q. (By Mr. Faes) Give you a second to review that. And my first question is: Have you seen this document before?

A. Yes, I have.

Q. Is this a document that you reviewed and relied upon in forming your opinions in this case?

A. Yes.

Q. Do you agree that -- let me read this. This is a document titled FDA strengthens -- strengthens requirement for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks. And it's dated January 4th, 2016.

Do you see that?

A. Yes.

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Q. It says beginning in the first paragraph, second sentence: The FDA issued one order to reclassify these medical devices from class II, which generally includes moderate-risk devices, to class III, which generally includes high-risk devices.
Do you see that?
A. Yes.
Q. Do you agree that surgical mesh to repair pelvic organ prolapse are high-risk devices?
A. No, I don't agree.
Q. So do you disagree with the FDA's decision to reclassify surgical mesh to a high-risk device?
A. Yes, I do.
Q. Do you believe that the Prosima is a high-risk device?
A. No, not at all.
Q. Do you believe that the Prolift is a high-risk device?
A. No, not at all.
Q. Do you believe the Gynemesh PS flat mesh is a high-risk device?
A. No.
Q. Do you know whether or not the Prolift is now classified as a class III -- strike that.

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Do you know whether or not the Gynemesh PS flat mesh is now classified as a class III or class II device?
A. I don't know.
Q. Do you think that would be important in -- or something you'd like to consider in forming your opinions regarding the Gynemesh PS?
A. No. I feel very comfortable with it with my experience and with the literature.
Q. Do you know whether or not Ethicon does internal risk analysis to determine risk scores for those devices -- strike that. I think I phrased that wrong.
Do you know whether or not Ethicon does internal risk analysis to determine risk scores for the medical devices they sell?
A. I'm not sure.
Q. You've never seen a residual risk analysis for the Prosima, Prolift or Gynemesh PS device?
A. I don't think I have.
Q. So you don't recall, sitting here today, whether or not Ethicon assigns a residual risk score when they do these analyses. Is that correct?
A. That's correct.

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Q. And you don't know obviously, then, if the number of this residual risk score correlates to the device being low risk, moderate risk or high risk?
A. I don't know.
Q. And, again, since you've never seen these, you don't know what Ethicon's assessment was for the Prolift, Prosima or the Gynemesh PS flat mesh with regards to whether it was a low, moderate or high-risk device. Is that correct?
A. That's correct.
Q. Now, if you look again at Exhibit No. 9, on the very first paragraph it says: Surgical mesh has been used by surgeons since the 1950s to repair abdominal hernias; in the 1970s, gynecologists began implanting surgical mesh for abdominal repair of pelvic organ prolapse and, in the 1990s, for transvaginal repair of pelvic organ prolapse. In 2002, the first flat mesh device with this indication was cleared for use as a class II moderate risk device.
Do you see that?
A. Yes.
Q. Do you know whether or not that the first mesh device with this indication that was cleared in

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2002 that it's referring to is the Gynemesh PS?
A. I don't know.
Q. So you don't know, sitting here today, whether or not the Gynemesh PS flat mesh was the first mesh device which was cleared with a transvaginal use indication?
A. I know it -- I think that was the year that it was approved and cleared, but I don't know if it was the first one.
Q. Good enough. Do you know if Ethicon wanted to sell the Gynemesh PS flat mesh with a transvaginal use indication today, if they would have to submit a premarket approval indication to the FDA because it's now a class III device?
A. Can you repeat your question, please?
Q. You know what, I'm going to strike that --
A. Okay.
Q. -- and move on. Doctor, on Page 3 of your report -- and feel free to refer back to it if you want. It's already marked as an exhibit. -- you state that the data in women does not support that the Gynemesh Prolene Soft degrades. Is that an opinion you intend to offer in this case?
A. Absolutely. I feel very strongly about that.

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Q. Would you agree that you are not an expert in polymer chemistry?
A. No, I would not agree with that. I mean, I have dealt with polymers all these years as a surgeon and I was a chemical engineering undergrad and studied polymer science there, so I feel comfortable with polymers and I understand how Gynemesh works in patients in over 2000 patients.
Q. So you hold yourself out as an expert in polymer chemistry. Is that right?
A. Yes, as far as it -- as far as it relates to my practice, I certainly do.
Q. Have you ever done any chemical testing with the Prolene Soft mesh or the mesh in the Prolift or the Prosima to see if it degrades?
A. No, I haven't done that.
Q. Have you ever done a microscopic analysis of the Prolene Soft mesh or the mesh that's in the -- which is the mesh that's in the Prolift or in Prosima to determine if it degrades?
A. No, I haven't.
Q. Do you -- strike that.
In support of your opinion regarding mesh degradation you state that the reoperation rates for

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recurrence are low and that cure rates and patient satisfaction is high. Is there anything else you believe supports your opinion?
A. Well, the literature definitely supports it when we don't see problems that can be related back to degradation in the literature.
Q. What do you believe the reoperation rates are for the Prosima device?
A. Oh, five percent, ten percent. And most of those are just small erosions that need to be repaired.
Q. What do you --
MR. GAGE: Object to form of the last question. I think you asked a question and the witness give a different answer, so that's all I'm saying.
Q. (By Mr. Faes) What do you believe the --
MR. FAES: Yeah, I think she answered about complications, not reoperation, so maybe I asked a bad question.
Q. (By Mr. Faes) What do you believe the reoperation rates -- strike that.
What do you believe the reoperation rates are for Prosima for mesh failure?

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A. For mesh failure -- what do you mean by "mesh failure"? Do you mean that the prolapse recurred?
Q. Yes.
A. In that same compartment or in another compartment?
Q. Well, let's -- both questions. What do you believe the reoperation rates are for Prolift for prolapse recurring in the same compartment, different compartment, and then both combined?
A. It's going to be -- for the -- the -- it's going to be around 20 percent per compartment.
Q. So I'm not sure if that answered my question, so I'll break it down. What do you believe are reoperation rates for Prosima for failures in the same compartment?
A. For a recurrent -- I don't call it a mesh failure, first of all, because it's not necessarily a fault of the mesh. It's just the way that the pelvis is. There's going to be a certain degree of recurrent prolapse no matter what technique you use.
Q. Let me see if I can re-ask the question in a way that you can answer with a straight percentage. What do you believe the reoperation rates are for the Prosima for treatment failure in the same compartment?

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A. Okay. So it's somewhere between ten to 20 percent.
Q. What do you believe the reoperation rates are for the Prosima for treatment failure in a different compartment?
A. About the same.
Q. What do you believe the reoperation rates are for the Prosima for treatment failure either in the same compartment or a different compartment?
A. It would be --
MR. GAGE: Object the form.
A. -- about the same, around that --
Q. (By Mr. Faes) Ten to 20 percent?
A. Around that range, yeah.
Q. And I think you already anticipated my question and answered it, but what do you believe the reoperation rates are for Prosima for mesh extrusion or -- strike that. I'm going to ask it a little bit different question.
What do you believe the reoperation rates are for the Prosima to treat complications, all complications, excluding treatment failure?
A. Excluding treatment failure, somewhere between five and ten percent.

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Q. What do you believe the reoperation rates are for the Prosima to treat complications or treatment failure in any compartment?
A. So somewhere between five and 20 percent. That's looking at the literature, looking at my own experience.
Q. So you -- as you sit here today, you don't believe that a reoperation rate for treatment failure of ten to 20 percent and a reoperation rate for complications of five to ten percent is evidence that the Gynemesh PS mesh in the Prosima degrades?
A. No, not at all. There's no correlation there.
Q. Is there a number it would reach -- it could reach in order for you to change or reconsider your opinion that the data in women doesn't support that the Gynemesh PS degrades?
A. I can't -- I can't even conceive of that, because it does not even -- it does not degrade in any way, so it's just a hypothetical question. So, yes, there's no --
Q. So if there --
A. There's nothing you could tell me that would make me say, oh, that's because of degradation,

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because it doesn't happen.
Q. But if I understand you correctly, you're using the -- you rely on the fact that reoperation rates for recurrence are low and cure rates and patient satisfaction is high is the basis for your opinion that the mesh doesn't degrade. Right?
A. Right.
Q. So you're saying -- telling me that there's no number that that -- that those reoperation rates could rise to that would cause you to reconsider your opinion?
A. No. I mean, that's part of the basis. That's not the whole basis. That's just -- first of all, we're starting with the fact that it doesn't degrade and then this is the supportive reason to show that it doesn't. But the converse is not necessarily true. If this happens, that doesn't mean that it degrades, if that makes sense.
Q. So, again, I think I asked you this question earlier -- maybe I didn't or maybe I've already forgotten the experts that your -- strike that. I'm just babbling now.
So let me just ask you a new question: In

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support of your opinion that the data in women does not support that the Gynemesh PS degrades, you state that the reoperation rates for recurrence are low, that the cure rates and patient satisfaction are high. Is there anything else that you're relying on to support your opinion that the data in women does not support that the Gynemesh PS degrades?
A. Well, also, apart from these, sort of, side studies where they show, quote, unquote, degradation, which I think is just probably the biofilm, in other studies, where they -- where they remove the mesh, the mesh is there. You know, it's not -- it doesn't disappear. It doesn't degrade over time. I mean, if Prolene degraded, they would not use it in cardiac surgery to rely on sewing together arteries. So this whole theory of degradation is just -- just bogus in my opinion.
Q. So if I understand you correctly, you're relying on literature to support your opinion that the Gynemesh PS doesn't degrade?
A. And my own clinical experience, my own clinical experience with my patient success and satisfaction with it. And in the cases where I've removed mesh, you know, grossly examining the mesh --

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yeah, I didn't do a microscopic electron microscopy on the mesh, but, you know, it's not like you see it disintegrating. It's not falling apart in front of your eyes.
Q. Have -- or do you believe that the mesh has to be disintegrating for falling apart in front of your eyes in order to have a clinical impact on the patient? Do you believe -- strike that. Let me ask a different question.
Do you believe that -- actually, let me start over.
Do you believe that polypropylene doesn't degrade at all or do you just believe that the polypropylene mesh in the pelvic organ prolapse products that you're offering opinion on -- opinions on don't grade?
MR. GAGE: Object to form.
A. I don't think it degrades at all. If it does degrade, microscopically, there's absolutely no clinical effect on patients --
Q. (By Mr. Faes) So your --
A. -- and there's no implication to it.
Q. Your opinion is that no polypropylene anywhere degrades?

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A. Like I said, if it does degrade, microscopically, there's no clinical impact, so it's a nonissue.
Q. I'm not sure if I got an answer to my question, though. Is it your opinion that no polypropylene anywhere degrades or do you agree that some polypropylene can degrade under the right circumstances?
A. I think it potentially could degrade under the right circumstances. Anything can degrade under the right circumstances. But does it clinically have any impact, no.
Q. Do you believe that when polypropylene mesh degrades, it can become -- strike that.
Do you believe that when polypropylene degrades one of the things that can occur is that the polypropylene can become brittle?
MR. GAGE: Object to form.
A. No.
Q. (By Mr. Faes) Do you know what fishing line is made out of?
A. No, I don't.
Q. You don't know that fishing line is made out of polypropylene?

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A. No, I didn't know that.
Q. Have you ever gone fishing?
A. Yes.
Q. Have you ever had to replace your fishing line because the line got brittle from the previous year?
A. Yes. But that's a completely different circumstance than something that's implanted in the body.
Q. Well, I wasn't asking about things that were implanted in the body. I'm asking -- so you'd agree with that example, that polypropylene under the right circumstances can degrade?
A. Yeah, sure.
Q. You also talked about the fact that polypropylene sutures are used -- or Prolene sutures, rather, are used in cardiac surgery. Do you believe that the environment in the vagina is the same as the environment in the cardiac cavity?
A. No. It's different.
Q. In fact, you know that there are peroxides present in the vagina and there are not peroxides present in the cardiac cavity. Right?
MR. GAGE: Object to form.

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A. Not to the same degree.
Q. (By Mr. Faes) Do you know whether peroxides have an effect on polypropylene degradation?
A. I believe that they can, yes.
Q. So, just so I understand your answer, you do believe that peroxides can accelerate or cause polypropylene to degrade?
A. In the right concentration, yes.
Q. What do you believe the patient satisfaction rates are for the Prosima device?
A. They're very high. They're 80 to 90 percent.
Q. And where are you getting that information from?
A. From multiple studies.
Q. What do you believe the reoperation rates are for the Prolift device for complications?
A. It's around the same as the Prosima, five to 20 percent.
Q. That's a pretty big range, isn't it, Doctor?
A. Yeah, and the studies are -- that's pretty much the range that you're going to find in the studies.
Q. Would you agree that the erosion or extrusion rate for the Prolift can range from 15 to 20 percent?

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A. Some studies show that, but most studies it's closer to the five to ten percent range. Eight percent seems to be the number that comes up a lot.
Q. So you did -- if someone were to tell you that the overall erosion or exposure or extrusion rates for the Prolift was in the 15 to 20 percent range, you'd disagree with that?
A. Yeah. That's -- that's high. I know some studies have shown that and have shown even higher in small studies, but -- but looking at the large database studies, the rates are not that high.
Q. Do you know Dr. Joe Carbone?
A. Yes.
Q. You've met Dr. Joe Carbone --
A. I have.
Q. -- before. Right? In fact, you both attended the 2011 Ethicon Pelvic Floor Summit in Sonoma together?
A. Yes.
Q. Where there was wine tasting and dinner?
A. Yes.
Q. So if Dr. Carbone told me last week that he believes the overall erosion or extrusion rates for the Prolift device is 15 to 20 percent, would you

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disagree with him?
A. With all due respect to Dr. Carbone, I think -- I don't think the literature bears out that -- that high a rate. And my personal experience certainly is not that high. And I think, talking to my colleagues, it's not that high.
Q. But you do agree that, at least in some studies, the erosion or exposure rate can be as high as 20 percent with the Prolift. Right?
A. I have seen studies that show that yes.
Q. And you're familiar with the Iglesia study?
A. Yes.
Q. And you know that the exposure and erosion rate for the Prolift in that study was greater that 15 percent?
A. Yes, as well as the suture exposure rate was also 15 percent in the native tissue repairs.
MR. FAES: I'm going to object and move to strike after the answer "yes." I didn't ask anything about suture exposure rates.
Q. (By Mr. Faes) And you know that that study was stopped by Dr. Iglesia and her colleagues because of their concern about the erosion and exposure rates. Correct?

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A. That's correct.
Q. Do you consider Dr. Iglesia an outlier?
A. Yes, I do.
Q. Do you know whether the FDA considers Dr. Iglesia and outlier?
A. I don't know what they think about Dr. Iglesia.
Q. So you've never seen records from meetings that Ethicon had with the FDA regarding the 522 orders where the FDA told Ethicon that they did not consider Dr. Iglesia an outlier. Is that fair?
MR. GAGE: Object to form.
A. You know, I've seen so many documents. As I sit here today, I'm not sure if I saw that or not. I probably did.
Q. (By Mr. Faes) So I'm going to ask a hypothetical: Assuming that the FDA said that they did not consider Dr. Iglesia an outlier, that's another instance in which you would agree with -- disagree with the FDA. Correct?
MR. GAGE: Object the form.
A. With all due respect to the FDA and Dr. Iglesia, I look at the full body of literature. I don't look at one study. I compare the full body of

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literature with my own experience and that's where I form my opinions, so I would have to disagree with them on that.
Q. (By Mr. Faes) Yeah. I'm going to have to re-ask it, because there's a lot of nonresponsive information in there. I'm going to ask a hypothetical: Assuming that the FDA said that they did not consider Dr. Iglesia an outlier, if they did indeed say that, that's another instance in which you would disagree with the FDA. Is that correct?
A. That's correct.
MR. GAGE: Object to form.
Q. (By Mr. Faes) What do you believe are the patient satisfaction rates with the Prolift device?
A. Again, very high, 75 to 90 percent.
Q. At what time frame? Are you calculating patient satisfaction rates at one year, three years?
A. Well, the -- you know -- studies go -- most -- a lot -- most of the studies are one to two years, but there are some studies that go out further to seven years.
Q. What's the longest study that you're aware of, the longest follow-up study you're aware of that utilized the Gynemesh PS mesh, whether it be in the

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Prolift or the Prosima or as a flat mesh?
A. I believe it's seven years.
Q. Do you recall what study or studies go out to seven years?
A. I would have to take a minute to refresh my memory.
Q. Do you recall, without refreshing your memory, whether it's more than one or if it's. . .
A. I believe there were two studies.
Q. Do you believe that if polypropylene mesh were to break down or degrade, it could lead to an erosion or an exposure?
A. We're talking hypothetically. And I would think that if it were degrading, then it would be just disappearing. And so I'm not sure how that could cause an erosion or an exposure.
Q. Do you believe that mesh degrading or breaking down could lead to an unintended tissue reaction?
A. Again, hypothetically, because as I stated before, I don't think it does degrade, but if there's some product that did degrade, then, yes, that could cause an inflammatory reaction.
Q. Can an inflammatory reaction or unintended

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tissue reaction cause the body to push the mesh out of the body causing it to be eroded or exposed?
A. Hypothetically, if there's an inflammatory reaction, you could have a tissue breakdown and have a mesh exposure. I wouldn't say it's pushing it out of the body, but there could -- if there's a tissue breakdown, you could have an exposure of the mesh.
Q. If polypropylene were to become brittle, as we discussed with the fishing line example, could that lead to an erosion?
A. I think it would depend on how it how it -- how it were oriented. And, again, I'm not conceding that it degrades or becomes brittle in the body. But hypothetically, if it were poking out towards the tissue, something could break down, I suppose.
Q. You'd agree that sharp edges of the mesh could cause an erosion?
A. If the mesh is not oriented properly and not placed properly, that could cause an erosion from a sharp edge. It's not because of the mesh. It's the way that it's put in.
Q. If the mesh becomes -- hypothetically, again, if the mesh becomes brittle, could that lead to patient discomfort?

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A. I'm not sure.
Q. On Page 3 of your report you state that Gynemesh PS has been the most studied mesh in pelvic reconstructive surgery. Is that an opinion you intend to offer in this case?
A. Yes.
Q. When you say that it's the most studied mesh in pelvic reconstructive surgery, what do you mean by that? Do you mean that it's had the most number of studies performed or that the -- had the most number of patients studied in those studies or both, if that makes sense? It's kind of an ineloquent question.
MR. GAGE: Object to form.
A. Both, the most studies, the most number of patients, the most randomized controlled studies.
Q. (By Mr. Faes) So what other meshes did you compare it to to make that determination that it was the most studied --
A. Well --
Q. -- in pelvic reconstructive surgery?
A. The Vypro, the PVDF, Ultrapro. And then there's other kits, as well, that are also polypropylene mesh, like the Elevate, that have been studied quite a bit, as well, but not as much as the

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Gynemesh, Prolift and Prosima.
Q. So, approximately, how many studies did you determine had been done on the Vypro mesh in pelvic reconstructive surgery?
A. I don't -- I don't have a number, but it's not many at all.
Q. How many studies did you find where PD -- PVDF mesh had been studied in pelvic reconstructive surgery?
A. I don't have a number.
Q. How many Ultrapro studies did you find that had been studied in pelvic reconstructive surgery?
A. I don't have a number for that.
Q. How many Elevate studies did you find that had been studied in pelvic reconstructive surgery?
A. I'm sorry. I don't have an exact number.
Q. So you can't quote a number as you're sitting here today, but you believe it's less?
A. Yes.
Q. Do you know if it's 50 percent less, 25 percent less?
A. It's a lot less.
Q. How did you determine it was less? What methodology did you use?

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A. Well, you can just do a PubMed search.
Q. Did you keep any documentation of your PubMed searches in terms of how many studies for these other four meshes?
A. No, I did not.
Q. Did you compare the Prolene -- actually, I'm going to strike that.
Different question: Did you do any kind of systematic review of the literature on those four meshes to determine whether the quality of those studies was better or worse than the quality of the studies on the Gynemesh PS mesh?
A. I just did sort of a survey of the studies. I didn't go in depth.
Q. So you'd agree that it wasn't any kind of a systematic review?
A. No.
Q. Did you compare -- in regards to this opinion, that it's the most studied mesh in pelvic reconstructive surgery, did you do any comparison to the traditional Prolene mesh, see how many studies there were where that had been used?
A. No, I didn't.
Q. Same question: The IntePro Lite mesh?

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A. No.
Q. What about the Marlex mesh, which is now called the Bard mesh?
A. Uh-huh.
MR. GAGE: You need to say "yes," not --
THE WITNESS: No. Yeah. I'm just acknowledging that I understood the question. Sorry.
A. No, I didn't.
Q. (By Mr. Faes) Would you agree that native tissue repair of pelvic organ prolapse is more studied than the Gynemesh PS has been in pelvic reconstructive surgery?
A. I am not sure about that. My gut feeling is that the Gynemesh is more studied, but I'd have to -- I'd have to -- I'd have to look at that.
Q. So -- but it's fair to say, as you sit here today --
A. Uh-huh.
Q. -- you've never looked at that and you don't know, one way or the other, whether native tissue repair for repair of pelvic organ prolapse is more studied than the Gynemesh PS has been in pelvic reconstructive surgery?
A. I don't know.

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Q. You haven't looked at that question?
A. I haven't looked at that.
Q. Okay. You also state in your report that there are numerous randomized controlled trials and over a hundred studies which demonstrate that the Gynemesh PS when used by itself or in the Prolift and Prosima devices -- I think I said that wrong. Strike that and I'll ask a new question.
You say in your report that there are numerous randomized controlled trials and over a hundred studies which demonstrate that the Gynemesh PS when used by itself or in the Prolift or Prosima devices. Is that correct?
A. That's correct.
Q. Do you know what the exact number is?
A. No, I don't.
Q. Do you have any documentation that you have or a list that you intend to refer to at trial as to what those greater than a hundred studies are?
A. None other than my reliance materials.
Q. But you've never separately broken them out, those hundred out of your reliance list for use as a demonstrative at trial or anything like that?
A. No.

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Q. Is that something you intend to do prior to trial?
A. Perhaps.
MR. FAES: I would ask counsel, if such a demonstrative is ever created, that that be produced to us.
Q. (By Mr. Faes) Do you know how many out of those hundred are randomized controlled trials?
A. I don't have a number off the top of my head. Numerous.
Q. Do you know how many of those studies are Gynemesh PS flat mesh by itself?
A. I don't have a number.
Q. Do you know if there have been any randomized controlled trials of Gynemesh PS flat mesh comparing it to comparator device or procedure?
A. I can't recall right now.
Q. Do you know if there are any randomized controlled trials comparing the Prosima device to an alternative device or procedure?
A. Yes, absolutely.
Q. How many of those -- how many randomized controlled trials do you believe there are that compare the Prosima device to a different device

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or procedure?
A. I believe there's about five or six.
Q. In the hundred studies that you say demonstrate the use of Gynemesh PS, when used by itself or in the Prolift or Prosima devices, do you know how many of those studies use Gynemesh PS abdominally rather than transvaginally?
A. I don't recall. Not very many.
Q. In your report you state that there -- you don't believe that there is any evidence that the Prolene mesh is cytotoxic. Is that correct?
A. That's correct.
Q. Is that an opinion you intend to offer in this case?
A. Yes.
Q. Have you studied what happens to tissue when it is exposed to a cytotoxic substance?
A. I'm sure in biology or in medical school we studied, you know, cytotoxicity and what happens to tissue in that circumstance.
Q. As you sit here today, can you tell me what the clinical effect would be to tissue if it were opposed [sic] to a cytotoxic substance?
A. Necrosis. Inflammation, necrosis.

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Q. Would you agree that necrotized or -- strike that.
Would you agree that necrotized tissue surrounding a mesh could lead to erosion or exposure of the mesh?
A. Yes.
Q. So isn't one clinical manifestation -- potential clinical manifestation of -- strike that.
So if you agree that one potential effect of being exposed to a cytotoxic substance is that the tissue can undergo necrosis and you agree that necrotized tissue surrounding the mesh can lead to an erosion or exposure of the mesh, isn't a study that shows an erosion or exposure rate of 15 to 20 percent evidence that the mesh is, indeed, cytotoxic?
MR. GAGE: Object to form.
A. No, not at all. The necrosis around the wound can be due to tissue handling, the state of the tissue, cautery of the edges, improper sewing technique, history of smoking, diabetes, poor blood flow. There's just innumerable reasons for necrosis. And most of the erosions are right in the suture line, so that's a wound healing issue. If it -- if mesh were cytotoxic, you would see erosions all over the

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place and you don't see that. You see them -- the vast majority are right in the suture line.
Q. You don't think a study that shows an erosion rate of 15 to 20 percent is an erosion all over the place?
A. No. No. I'm talking about -- I'm talking about erosion on the side of the vagina, you know, not just in the suture line. If it's in the suture line, that's a wound healing problem. If it -- if the mesh were cytotoxic, you would see holes on this side of the vagina and over here, not just in the incision line.
Q. So is it your testimony that you've never seen an erosion any place other than in the incision line?
A. No, I'm not saying that. I'm not saying that at all. I have seen that on the sides. Usually an arm that was not placed properly through the sulcus, but --
Q. I think you've you've answered my question.
A. Okay.
Q. I'm going to move to strike everything after that anyway, but --
A. Okay.

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Q. -- if you want to keep going, I won't cut you off. So you've listed multiple potential causes of tissue necrosis. We can agree that there are multiple potential causes of tissue necrosis. Correct?
A. Yes.
Q. And we can also agree that one potential cause of tissue necrosis is the tissue being exposed to a cytotoxic substance. Is that correct?
A. That's correct.
Q. On Page 4 of your report you state that plaintiffs' experts have said that there are safer or better meshes, that these meshes have not been demonstrated to be more efficacious based on reliable scientific literature like the Gyne -- the Gynemesh PS. Is that correct?
A. That's correct.
Q. Is that an opinion you tend to offer in this case?
A. Yes.
Q. Now, specifically, in your report, you mention DynaMesh, Vypro and Ultrapro. Is that right?
A. Correct.
Q. Are there any other meshes that you have

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studied that you believe have not been demonstrated to be more efficacious based on reliable scientific literature like the Gynemesh PS?
A. No.
MR. GAGE: Just take a quick bathroom break.
MR. FAES: Same here. Let's do it real quick.
THE WITNESS: Yeah.
(Break.)
Q. (By Mr. Faes) Dr. Pramudji, we're back on the record after a short break. Are you ready to proceed?
A. Yes.
Q. Before the break we were talking about meshes that you believe have not been demonstrated to be safer and more efficacious based on the reliable scientific literature like Gynemesh PS. Did you study the Restorelle mesh?
A. No, I did not.
Q. And that's currently your mesh of choice for ASC. Correct?
A. Yes, that's correct.
Q. Did you study the IntePro mesh?

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A. No, I did not.
Q. Did you study the IntePro Lite mesh?
A. No.
Q. Did you study the Elevate mesh?
A. No.
Q. What about the Uphold mesh?
A. No.
Q. No. Did you know that Ethicon was developing a Prosima Plus M device which would have used the Ultrapro mesh, rather than the Gynemesh PS mesh just like the Prolift Plus M?
A. Yes, I was aware of that.
Q. When were you made aware of that?
A. Pretty early on, because we were -- we were asking for it, because we liked the Prolift Plus M mesh and we were wondering why the new product was made with the Gynemesh PS versus the Prolift Plus M mesh.
Q. Do you anticipate that if the Prosima Plus M had been made available with the Ultrapro mesh, do you believe that would have become your device of choice over the traditional Prosima, just like the Prolift Plus M became your device of choice over the Prolift?
MR. GAGE: Object to form.

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A. I'm not sure. I would have to try it out and see if I got similar results with it.
Q. (By Mr. Faes) Do you know why the Prosima Plus M device ultimately never came to market?
A. I don't know why.
Q. Can you -- well, this is going to be an easy question because there's hardly any kits left on the market, but can you point to a kit for the repair of pelvic organ prolapse which is on the market today which uses a mesh that is heavier in weight than the Gynemesh PS mesh?
MR. GAGE: Object to form.
A. No, I can't.
Q. (By Mr. Faes) In fact, as you sit here today, do you know that all of the mesh kits still on the market have mesh that are lighter in weight than the Gynemesh PS mesh?
MR. GAGE: Object to form.
A. I think they're very similar, maybe slightly lighter.
Q. (By Mr. Faes) But, certainly, none are heavier than the --
A. That's correct.
Q. -- Gynemesh PS mesh?

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MR. GAGE: Object to form.
A. I'm sorry to interrupt. Yes, that's correct.
Q. (By Mr. Faes) Do you know what the weight in grams per meter squared of the Gynemesh PS mesh is?
A. I can't remember at this moment. I used to know. I'd have the look it up.
Q. On Page 5 you state -- of your report you state that the Prosima is minimally invasive compared to the abdominal -- abdominal sacrocolpopexy and less morbid. Is that an opinion you intend to offer in this case?
A. Yes.
Q. First of all, let me ask you this: What do you mean by less morbid?
A. Less effect on the body. With the sacrocolpopexy, you have more dissection, you have more risk of bowel complications compared to Prosima.
Q. Is there anything else about the ASC procedure that you believe is more morbid than the Prosima procedure?
A. It also has a risk of hernia, injury to major vessels, bowel obstruction, adhesions.
Q. Do you believe that the Prosima device doesn't carry with it a risk of hernia?

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A. I'm talking about abdominal wall hernia, to be clear.
Q. Okay.
A. So because of the trocars or the incision for an abdominal sacrocolpopexy, there's going to be a risk of abdominal wall hernia.
Q. And is that a risk that -- is that not a risk of the Prosima device in your opinion?
A. Right, because there's no abdominal wall incision for a Prosima.
Q. Can -- is -- can the Prosima device cause other hernias, such as an inguinal hernia.
A. No, it cannot cause that.
Q. Do you believe the Prosima device doesn't have a risk of bowel injury?
A. It's a very small risk. If you have apical dissection into an enterocele, it could happen. Or if you're doing a posterior Prosima, you have a risk of rectal injury, but it's a very small risk.
Q. Do you believe it's a --
A. And it's --
Q. -- smaller risk than the risk of bowel injury with the ASC?
A. Yes, much smaller risk.

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Q. Now, you state that the Prosima device is less invasive. Would you agree that a doctor or patient might choose a more invasive surgery to avoid potentially life complications of a less invasive device or procedure?
A. What are "life complications"?
Q. Did I say life com -- I meant life-changing complications.
A. Oh, okay.
Q. So let me -- did -- is that not what I said?
MR. GAGE: Yeah, I'm going to -- if you're going to rephrase -- if you'll withdraw and rephrase the question.
MR. FAES: Yeah, I'll withdraw it and rephrase it.
MR. GAGE: Thank you.
Q. (By Mr. Faes) Would you agree that a doctor or patient might choose a more invasive surgery to avoid potentially life-changing complications of a less invasive device or procedure?
A. Yes, I agree with that statement.
Q. Would you agree that a doctor and patient should know about all of the potentially life-changing complications of the device or the procedure, so they

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can make an informed choice about what device or procedure they would like to have performed on them?
A. I think a doctor and their patient need to know about potential complications that can occur with any surgery that they're going to have, knowing realistically that you may not be able to anticipate rare complications.
Q. But even if a complication is rare, you would -- if it's potentially life-changing or devastating, you would agree that it's important for both the doctor and patient to know about that, in order to make an informed choice about whether they want to proceed with that surgery?
A. Yes, that's fair.
Q. Would you agree that if a -- even if a Prosima device is placed correctly by a surgeon, the vaginal support device can fall out on its own before the 21-day prescribed healing period has lapsed?
A. That can happen, yes, depending on how their body handles the micral suture.
Q. Would you agree that if an infection occurs around the vaginal support device, removal of that vaginal support device is indicated and necessary even if the prescribed 21 days had not passed since it was

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placed?
A. I can agree with that, although I would say that I've never seen that or heard of it, but hypothetically, that -- I would agree with that statement.
Q. You've never seen or heard of a vaginal support device that needed to be removed prior to the 21 days elapsing because of an apparent infection?
A. No.
Q. That's not cited on Page 41 of your report in an article?
A. Oh, I was talking about my own experience. Sorry.
Q. Oh, okay.
A. Yeah.
Q. Okay. So you're aware that that --
A. Yes.
Q. -- that can occur?
A. Yes.
Q. Now, you've testified before that you're familiar with the ProteGen project -- ProteGen product. Correct?
A. Correct.
Q. And you testified that you know that the

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ProteGen was removed from the market because the erosion rates were unacceptably high?
A. That's correct.
Q. Do you know what the reported rates of erosion were for the ProteGen?
A. I can't recall right now.
Q. How high would the erosion and exposure rates for the Prosima need to be in order for you to say the erosion rate was unacceptably high?
A. I think I would feel uncomfortable if I were seeing an erosion rate upwards of 30 percent.
Q. So if the erosion rate for the Prosima were 25 percent, you wouldn't say that that was unacceptably high?
A. No.
Q. One in four patients had an erosion or exposure?
A. I would -- I would think twice about it and it would depend on how bad the erosions were and what kind of treatment they needed and who -- who they are, because as you know from the literature a lot of patients can live their -- with an erosion, a small erosion. So there's a few factors to take into consideration. That's kind of a gray area. You have

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to take everything into consideration.
Q. But anything 30 percent or higher --
A. Yeah.
Q. -- with the Prosima you would find unacceptably high?
A. I think, if I had one in three, that would -- that would be a little bit high.
Q. Is your answer the same for the Prolift device?
A. Yes.
Q. Is it the same for the Gynemesh PS flat mesh?
A. Yes.
Q. Do you intend to offer an opinion in this case as to whether the warnings in the Prosima IFU were sufficient to apprise doctors of the risks of this product?
A. Yes, I believe they were sufficient.
Q. Do you know what the standards were that Ethicon applied in terms of what needed to be included in the warnings about the Prosima?
A. Yes.
Q. And what standards do you believe Ethicon applied regarding what needed to be included in the warnings about Prosima?

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A. I think they were -- you know -- excuse me -- complications that had a certain degree of frequency and severity and anything that could potentially be life changing that they would try to include.
Q. I apologize if you've been asked these next couple questions before, but you've been deposed, what, five times and I can't remember everything you said.
MR. GAGE: Perfect. Perfect.
Q. (By Mr. Faes) Have you ever in your career been involved in writing or preparing writings for a medical device?
A. No.
Q. That's wrong in my outline. Have you ever been in your career involved in writing or preparing IFUs for a medical device?
MR. GAGE: Object to form.
A. No, I have not.
Q. (By Mr. Faes) In your practice, do you typically read the IFU for each mesh kit or device that you use before using it?
A. Yes, I do.
Q. You don't read -- do you -- you don't read the IFU every time you use the device. Correct? You

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just read it for the first time?
A. That's correct.
Q. If something in the IFU changes, is there any way that you would know if the information in the IFU had changed?
A. Not unless someone told me about it.
Q. In all your years implanting products for -- strike that.
In all of your years of implanting products manufactured by Ethicon, has any Ethicon representative or sales rep or anybody whoever -- who works for Ethicon ever came to you and told you that the IFU for a product had been updated?
A. Not that I can recall.
Q. Do you know if the Prosima IFU was ever updated?
A. I'm not sure about that one.
Q. Do you know if the Gynemesh PS IFU was ever updated?
A. I can't recall.
Q. Do you know if the Gynemesh PS IFU was updated this year?
A. Not that I can recall right now.
Q. When you read an IFU, do you assume that the

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IFU is disclosing to you each of the risks and complications the company knew could occur with the kit or device that you're using?
A. No, because I also take into consideration my surgical training and I know that there's some risks of surgery that aren't going to be -- aren't going to be included there, so I don't rely on the IFU to tell me all the risks.
Q. Do you assume that when you read an IFU from a company regarding a mesh kit or medical device that the company is disclosing to you those complications and risks that could be significant for the patient and known to the company?
A. Again, not necessarily because there's some that you just apply your surgical training to and you take that into consideration and assume that those are going to be some of the risks.
Q. Do you assume that when you read an IFU for a medical device that the company was disclosing any risks and complications that would be inherent to the mesh material, so that you would know what those risks are?
A. Yes, I would assume that they would -- they would include -- include those sorts of things

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specific to the device.
Q. Do you know whether or not -- strike that.
Do you know whether or not one of the purposes of the IFU is to disclose each of the risks and complications that can occur with the use of that mesh kit in a woman's body?
MR. GAGE: Object to form.
A. I think it's to -- to communicate the risks, but it's not meant to be comprehensive and I don't think surgeons take it to be comprehensive either.
Q. (By Mr. Faes) As you sit here today, do you have an understanding of any standard whatsoever as to what risks and complications are supposed to be disclosed in an IFU?
A. I believe there are some guidelines from the FDA that help guide companies in what they should put into the IFU.
Q. Do you know what those guidelines are called?
A. No, I don't know what they're called.
Q. Do you know if you've reviewed those guidelines before?
A. I have seen them before, yes.
Q. Would you agree that your background and experience is not necessarily the same as other

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doctors who use medical devices or might consider using the Prosima?
MR. GAGE: Object to form.
A. Well, of course, there's going to be a wide range of doctors that might use medical devices. There's going to be some that are very -- more experienced than others.
Q. (By Mr. Faes) You'd agree that you might know about a complication from a particular mesh device or kit from your own experience that another doctor might not know about?
A. I don't know if I would agree with that. I think that if you're a pelvic surgeon, if you're -- you're doing operations and you've been through residency, then you would be aware of the potential complications. You may not have experienced it. The more surgery you do, the more you're bound to have complications along the way, but you would be aware of it.
Q. So if you knew about a potential risk or complication from the Prosima or Prolift device that another physician didn't know about, would you consider that physician to not be a diligent and reasonable physician for not knowing about that?

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A. I think it would depend on what -- you know -- what you're talking about, what sort of situation you're talking about.
Q. So you'd agree that it's possible that a -- there could be a situation where a physician wouldn't know about a potential risk or complication of the Prosima or Prolift that you did know about and that doctor could still be a reasonable and prudent physician and be doing his work within the standard of care?
MR. GAGE: Object to form.
A. I think people have, you know, different training in their residency, different experience, so it's possible, but I think it's unlikely, because I think any reasonable pelvic surgeon would be able to anticipate the potential complications of pelvic -- any pelvic surgery, whether it's with a kit or native tissue or whatever technique that you're using.
Q. (By Mr. Faes) So is --
A. I don't think you would be surprised by pelvic pain or be surprised by poor wound healing. That should be anticipated.
Q. So is it your testimony that if there was a risk or complication of the Prosima or Prolift device

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that a physician didn't know about, that that physician wasn't reasonable and prudent, using your words?
A. I don't think I used those words, but. . .
Q. I think you said reasonable, so let me --
A. Okay.
Q. -- let me strike that and I'll ask it again.
A. Okay.
Q. So is it your testimony that if there is a risk or complication of the Prosima or Prolift device that an implanting physician didn't know about, that that physician wasn't reasonable in his treatment and care?
MR. GAGE: Object to form.
A. I would have to say that they're missing -- they may be missing some knowledge or experience.
Q. (By Mr. Faes) Yeah. My question is actually a little different than that.
A. Okay.
Q. My question isn't whether their -- whether they're missing knowledge and experience. My question is whether you consider them to not be reasonable in their treatment and care of a physician -- of a patient if there was a risk or complication of the

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Prosima or Prolift device that they didn't know about.
MR. GAGE: Object to form.
A. No, I disagree because they could still be reasonable, they could still be giving the patient good treatment and care even if they didn't know about that risk or complication.
Q. (By Mr. Faes) In doing your work on this case, have you ever been curious as to what the regulatory affairs professionals department in Ethicon, the professionals who are required to make sure an IFU complies with FDA regulations, are you -- have you been curious about what they thought needed to be in an IFU?
MR. GAGE: Object to form.
A. Not really.
Q. (By Mr. Faes) That's not something that you thought would be helpful in forming your opinions in this case, that the Prosima and Prolift and Gynemesh PS IFUs are adequate?
A. No, because I think they're adequate. I think that they did adequately warn about potential complications, so I think they did a fine job putting it together.
Q. Would you agree with me that if Ethicon

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medical affairs knew that there was a potential risk or complication attributable to the Gynemesh PS mesh, itself, which, if occurred, could cause severe permanent injury to a woman, that risk should be disclosed in the IFU? Would you agree with that statement?
A. No, because they're going to have multiple discussions and opinions and bouncing things back and forth and I think that what they put in the IFU is perfectly adequate and reliable.
Q. Have you ever studied the question of what risks and complications were known to doctors across the country with various backgrounds and levels of experience with regard to the use of the Prosima?
A. No, I have not studied that.
Q. Same question: Gynemesh PS?
A. No.
Q. Same question: Prolift?
A. No.
Q. Same question: Prolift Plus M?
A. No.
Q. I know you're not giving an opinion on, but. . . Do you agree that -- well, actually, I think I know your answer to this. I'm going to strike that

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and start over.
Do you agree that mesh shrinkage or contraction can lead to severe pelvic pain?
A. No.
Q. Do you believe that wound contraction can cause -- strike that.
Do you agree that wound contraction or scar contraction around a mesh can lead to severe pelvic pain?
A. Yes.
Q. Do you agree that -- strike that.
Do you agree that wound contraction or scar contraction surrounding mesh can lead to painful sexual intercourse?
A. (No response.)
Q. Do you want me to restate it since you can't read it?
MR. GAGE: It's hard to read on the screen here.
MR. FAES: Yeah.
A. Please.
Q. (By Mr. Faes) Do you agree that wound contraction or scar contraction surrounding the mesh can lead to painful sexual intercourse?

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A. Yes. And it can also occur with wound contraction without mesh. It occurs in native tissue repairs, as well.
MR. FAES: Object and move to strike after the answer "yes."
Q. (By Mr. Faes) Same question: Inability to -- with regard to inability to engage in sexual intercourse?
MR. GAGE: Object to form.
Q. (By Mr. Faes) Since he's going to object to the form, I'll withdraw that and ask the whole question. Would you agree that wound contraction or scar contraction surrounding the mesh can lead to inability to engage in sexual intercourse?
A. I don't think that there would be a case where that would -- would occur, where they would be unable to engage in sexual intercourse.
Q. But you did agree that it can cause painful sexual intercourse?
A. Yes, pelvic -- pelvic surgery scarring can cause painful intercourse.
Q. Would you agree that intercourse can be so painful to where a person is unable to engage in sexual intercourse?

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A. Uninterested, unwilling, but not unable. It's not as if the vagina is completely closed, but if it's -- if you're saying because of pain, then, yes, where they would be un -- unwilling, uninterested. Physically, they would be able to have intercourse, but it would be too painful.

Q. So you make a distinction between someone who is unable to have sexual intercourse because it's too painful versus someone who is just physically unable to have intercourse?

A. Well, yes. I mean, there are -- especially with native tissue repairs, there are situations where the vagina is so scared and contracted where they are physically unable to have intercourse, not just because of pain, because they -- their vagina is absolutely too small.

Q. Okay. So you're --

A. And I don't --

Q. -- you're making a distinction, not to be indelicate, but between someone who is physically unable to be penetrated and someone who --

A. Has --

Q. -- prefers not to be because it's too painful.

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A. Right.

Q. Is that right?

A. Yes.

Q. Would you agree that one of the risks of the -- I'm going to strike that and ask if we can agree to something, so I don't have to re-ask these questions three different times. For the purposes of these questions, as we discussed earlier, when I refer to the pelvic organ prolapse products, I'm referring to the Prolift, the Prosima and the Gynemesh PS, which are the three products that you're offering an opinion on. If you can't answer the question the same way for all three products, let me know and then I'll have to go through each three separately. Can we agree to that?

A. Yes.

Q. Would you agree that one of the risks of the pelvic organ prolapse products is that they can lead to complex mesh erosions?

MR. GAGE: Object to form.

A. Yes, that is a risk.

Q. (By Mr. Faes) Would you agree that one of the risks with the pelvic organ prolapse products is that they can lead to chronic pain syndrome?

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A. Yes, as in all pelvic surgery.

Q. Would you agree that one of the risks of the pelvic organ prolapse products is that they can lead to dyspareunia?

A. Yes, as in all pelvic surgery.

MR. FAES: Move to strike after the answer "yes."

Q. (By Mr. Faes) Would you agree that one of the risks of the pelvic organ prolapse products is that they can lead to multiple surgical interventions to treat the complications?

A. Yes, that can occur.

Q. Would you agree that one of the risks of the pelvic organ prolapse products is that a woman can sustain life-changing complications as a result of those products?

A. Yes, that can occur.

Q. Would you agree that one of the risks of the pelvic organ prolapse products is erosions at multiple sites?

A. Yes.

Q. Would you agree that with the pelvic organ prolapse products, most women who have erosions or extrusions require surgical intervention?

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A. Yes.

Q. Would you agree that with the Pros -- or strike that.

Would you agree that with the pelvic organ prolapse products multiple attempts to excise the mesh may be required?

A. Yes.

Q. Would you agree with the pelvic organ prolapse that one of the risks is life-changing complications?

MR. GAGE: Object to form.

A. Yes.

Q. (By Mr. Faes) Would you agree that one of the risks of the pelvic organ prolapse products is incapacitating pelvic pain?

A. Yes, as in all pelvic surgery.

MR. FAES: Move to strike after the answer "yes."

Q. (By Mr. Faes) Would you agree that one of the risks of the pelvic organ prolapse products is large scale erosions that are not easy to resolve?

A. There's a very remote risk.

Q. But is the answer yes?

A. Yes.

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Q. It is risk. The list of complications and risks that I just asked you about, do you know whether or not Ethicon knew about all those risks on the day the pelvic organ prolapse products first went on the market?
A. I can't recall.
Q. So you don't know, one way or the other, sitting here today?
A. I don't -- yes, I don't know.
Q. If they did know, do you agree that those risks should have been in the IFU?
A. I think those are risks that pelvic surgeons would anticipate, because as I stated, most of those risks, with the exception of the erosion, are risks of pelvic surgery.
Q. Okay. I didn't ask about whether they were risks that pelvic surgeons would anticipate. My question was very specific. My question was: If Ethicon did know about those risks, do you agree that those risks should have been put in the IFU?
MR. GAGE: Object to form.
A. I don't think they needed to be in the IFU, because the surgeons with their knowledge and being professionals would be able to anticipate that.

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MR. FAES: Move to strike after the word "IFU."
Q. (By Mr. Faes) And that's your opinion for all of the risks that we just went through today?
A. Yes.
Q. When the Prosima first came onto the market, surgeons were not experienced on any long-term basis with implanting mesh with a vaginal support device. Correct?
A. That's correct.
Q. Do you know the area of the -- do you know the square area of the mesh used in the Prosima kits?
A. Not off the top of my head, no.
MR. GAGE: Object. Form.
Q. (By Mr. Faes) And I think you've already answered this question: You don't know what sizes and configurations the Gynemesh PS mesh is offered in. Correct?
A. That's correct.
MR. GAGE: I show about eight minutes before she needs to go.
MR. FAES: Okay.
MR. GAGE: And we can sort out at 4:20 how much -- did you get three hours in, did you not.

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MR. FAES: Yeah, I think -- yeah, yeah, yeah, yeah. That's fine.
MR. GAGE: Because you might be entitled to a few more minutes. I don't know.
MR. FAES: Yeah, I think ten. Anyway. . .
Q. (By Mr. Faes) Would you agree with the way -- strike that.
Would you agree that compared to the way the mesh was used before the Prolift, the Prolift provided for more mesh to be put in a woman's pelvis than had been previously used?
MR. GAGE: Object to form.
A. I think it depended on how that surgeon was configuring the Gynemesh supplementation, so it could be the same, it could be more, it could be less.
Q. (By Mr. Faes) Do you believe that there is a sheet of Gynemesh PS flat mesh available as a single sheet that is more area than the mesh in the entire Prolift kit?
A. Oh, in the Total Prolift?
Q. Yes.
A. No. I think the Total Prolift is probably more. I'm thinking about one compartment at a time.

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I think if you combine -- you -- you know -- combined an anterior and posterior Gynemesh, it would probably be more than a Prolift, Total Prolift.
Q. Okay. What about just one Prolift, just the anterior or just the posterior, do you believe that there's a sheet of Gynemesh PS that's available that would be more mesh, in terms of total square area than either the anterior Prolift with the arms included or the posterior Prolift with the arms included?
A. Yeah. I think it would probably be very similar once you added it together. And whenever you do a Prolift, you usually trim a lot of the mesh --
Q. What --
A. -- on the tail or on the sides.
Q. What size Gynemesh PS would that be that would greater than the Prolift?
A. I mean, I think one size was, I think, ten by ten centimeters, if I remember correctly. And so it just depends on how the surgeon fashioned it. So it could be more, it could be less.
Q. Do you know if there's more mesh in an anterior or posterior Prolift than what would be contained in a ten by ten centimeter strip of Gynemesh PS?

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A. It's less, the anterior Prolift? The anterior Prolift is bigger than a posterior, yeah.
Q. What do you believe the area of the posterior Prolift is?
A. I don't know off the top of my head. I mean, I'm just picturing it from having used it. It's not ten by ten centimeters.
Q. So you don't --
A. It's much less than that, even if you add the arms.
Q. You don't know the total area with the arms, but you -- but you believe it's less than ten by ten centimeters?
A. Absolutely.
Q. You believe it's less than a hundred square centimeters?
A. Absolutely.
Q. Is the same -- is the answer --
A. Because you trim it. You don't use the whole thing. And you trim the arms.
Q. Do you know if when physicians use a ten-by-ten sheet of Gynemesh PS, whether or not they typically trim it or typically use the entire square of mesh?

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A. They typically trim it. That's what I said earlier, it could be the same, it could be more, it could be less.
Q. So you disagree that, compared with the way the mesh was typically used before the Prolift, the Prolift provides for more mesh to be put in a woman's pelvis than had been previously used before Prolift kits were available?
MR. GAGE: Object to form.
A. Correct, I disagree with that.
Q. (By Mr. Faes) But only with -- only if just the anterior or posterior is used by itself?
A. Well, if -- okay. If you -- yeah, comparing one compartment to one Gynemesh graft, yeah, comparing one. But if you did a Gynemesh graft in each compartment --
Q. Right. So --
A. -- that would be the comparison. I wouldn't compare one Gynemesh graft to a Total Prolift.
Q. So would you agree that, compared to the way the mesh was used before the Total Prolift, the Total Prolift provided for more mesh to be put in a woman's pelvis than had generally previously been used?
A. I feel like we're going in circles. It just

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depended on how that surgeon used the Gynemesh. So if they're using a Total Prolift, they would have potentially used two Gynemesh grafts on that same woman previously, so it could still be the same, more or less, depending on how they cut their Gynemesh and how they utilize it.
Q. Okay. Let me ask you this question --
A. Okay.
Q. -- would you agree that compared with the way mesh was used for the repair of pelvic organ prolapse before the transvaginal mesh technique with the Gynemesh Prolene Soft, the Prolene Soft provided for more mesh -- strike that.
Would you agree with me that compared with the way mesh was used for the repair of pelvic organ prolapse before the transvaginal mesh technique using the Gynemesh Prolene Soft was developed, the transvaginal technique with Gynemesh Prolene Soft provided for more mesh to be put in a woman's pelvis than had been previously used for pelvic organ prolapse repair?
MR. GAGE: Object to form.
A. I can't really answer that, because there was no standardized way to do that surgery before.

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Q. (By Mr. Faes) So is the answer to my question you can't -- you can't answer one way or another, you just don't know?
A. It's a question that cannot be answered because it was not a standardized technique.
Q. If Ethicon medical affairs believed that a caution needed to be taken by a doctor before using Prosima in a particular class of women, should that have been put in the IFU?
A. I would say yes to that.
Q. If Ethicon -- I think I'll ask two more questions and then you probably gotta get out of here. Right? Okay. Unless you need to get out of here right now. Two more questions --
MR. GAGE: The real clock is faster than my watch yes.
MR. FAES: Okay.
MR. GAGE: Yeah.
Q. (By Mr. Faes) If Ethicon medical affairs believed that a caution should be used before putting a Prosima into a woman based on some fact about her demographics or her age or her level of prolapse or comorbidities or anything that was specific that could be related to specific patients, should that

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information have been in the IFU, so that doctors would have that information when deciding to do with their patients?

MR. GAGE: Object to form.

A. I don't --

Q. (By Mr. Faes) Deciding -- I think I flubbed the end of that question. I meant to say deciding what to do with their patients. I don't know if the realtime is wrong or I'm wrong, but do you want me to answer the -- re-ask the question? It's a long one.

A. Please.

Q. We'll make this the last question then.

A. Yeah.

Q. If Ethicon medical affairs believed that a caution should be used before putting a Prosima into a woman based on some fact about her demographics or her age or her level of prolapse or comorbidities or anything like that was specific that could be related to specific patients, should that information have been in the IFU, so doctors would have that information when deciding what to do with their patients?

MR. GAGE: Object to form.

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A. Again, it goes back to, what do you need to put in the IFU, because that's why we're physicians. We're professionals. We're trained to make these judgment calls. I mean, I think it -- I think that the IFU is perfectly adequate. I don't think anything was left out, so I can't think of what they would come up with that would change that opinion that I would say -- I would say no to that question, because, again, they're going to be discussing things back and forth and bouncing ideas off of each other. That doesn't all need to go into the IFU.

Q. (By Mr. Faes) But if Ethicon medical affairs believed that that caution should be put in there, you believe that that information doesn't need to be included, even if Ethicon medical affairs believes it needs to be put in there?

MR. GAGE: Object to form.

A. As I already answered, I would say no.

Q. (By Mr. Faes) If Ethicon medical affairs believed that a particular warning or caution should be added to the IFU, but that caution or warning wasn't added due to marketing reasons, would you agree that that would be wrongful?

MR. GAGE: Object to form.

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A. Not necessarily.

Q. (By Mr. Faes) You say not necessarily. Are there --

A. Uh-huh.

Q. -- are there situations where you believe it would be appropriate to not include a warning or precaution that medical affairs thought should be in the IFU for marketing reasons?

MR. GAGE: Object to form.

A. It depends on -- it depends on what it was. You know, when they're coming up with these things, they're taking in numerous considerations, so it would -- it would just depend on what it was. It would -- it would give me some pause if that was the only reason for marketing reasons, but I would have to know more specifics before I drew a conclusion about it.

Q. (By Mr. Faes) So if medical affairs said, I think this warning or precaution is really important and marketing comes in and says, yeah, but it's going to hurt the sales of our product, so we're not going to put it in, you believe that there are situations where that would not be wrongful?

MR. GAGE: Object to form.

A. Right, because as I've said before, there's

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some risks that are not in an IFU for any product that surgeons are aware of, like death. Death is a risk of any surgical device with surgery. You know, surgery has a risk of death, so they may not want to put that in there for marketing reasons.

Q. (By Mr. Faes) So you believe that there are situations where it's appropriate for marketing to override the judgment of medical affairs?

MR. GAGE: Object to form.

A. I don't -- I don't -- I don't want to agree with that. I mean, I don't want to disagree with that because medical affairs should be the priority, but there are so many considerations that go into it.

MR. FAES: I'll object and move to strike after the word "priority." And Doctor, I'll let you go, because --

THE WITNESS: Okay.

MR. FAES: -- I'm sorry. I asked way more questions than I intended to. We got into a --

THE WITNESS: I know. We were on a roll there.

MR. FAES: We got into a thing there.

THE WITNESS: Yeah.

MR. GAGE: All right. So we're off the

record now.
(Deposition concluded at 4:25 p.m.)
(Signature reserved.)
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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
CHRISTINA PRAMUDJI, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

THE STATE OF TEXAS:
COUNTY OF FT. BEND:

I, Tamara Vinson, a Certified Shorthand Reporter and Notary Public in and for the State of Texas, do hereby certify that the facts as stated by me in the caption hereto are true; that the above and foregoing answers of the witness, CHRISTINA PRAMUDJI, M.D., to the interrogatories as indicated were made before me by the said witness after being first duly sworn to testify the truth, and same were reduced to typewriting under my direction; that the above and foregoing deposition as set forth in typewriting is a full, true, and correct transcript of the proceedings had at the time of taking of said deposition.

I further certify that I am not, in any capacity, a regular employee of the party in whose behalf this deposition is taken, nor in the regular employ of his attorney; and I certify that I am not interested in the cause, nor of kin or counsel to either of the parties.

GIVEN UNDER MY HAND AND SEAL OF OFFICE, on this, the ____ day of March, 2016.

_____
Tamara Vinson, Texas CSR No. 3015
Expiration Date: 12-31-2016

GOLKOW TECHNOLOGIES, INC.
Texas CRCB Registration #690
440 Louisiana, Suite 910
Houston, Texas 77002
www.golkow.com

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